

IMPLANTABLE COLLAMER LENS (ICL) FOR CORRECTION OF MYOPIA

MS OPOHTHAL

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ACKNOWLEDGEMENT

I would like to express my profound gratitude to our Director **Dr. C.A Nelson Jesudasan, M.S., D.O.M.S, F.R.C.S.(Glasgow &Edinburgh)**, ICEH, Joseph Eye Hospital, Trichy for guiding me throughout and providing me enabling atmosphere and facilities to complete my study.

I am really indebted to **Dr. Pragya Parmar, M.S.**, Professor for being my guide and assigning me this topic, for her guidance, patience, corrections, constant support and encouragement.

I am grateful to **Dr. Amjad Salman, M.S.**, Registrar, for his guidance, stellar support and inspiration at every step. He was always at hand to clear all my doubts.

I would like to thank **Dr. C.M. Kalavathy, M.S, D.O.**, Professor and HOD of Cornea, for being my co-guide and helping me and guiding me in this study.

I would like to express my gratitude towards **Dr. Philip Thomas, M.D, Ph.D.**, Professor and HOD, Microbiology, for his constant guidance, help and technical inputs for dissertation writing.

I am also grateful to **Dr. M. Rajamohan, M.S., D.O., CCEH (LONDON)** for his inspirational guidance and support.

I would also like to express my heartfelt thanks to **Dr. M. Prathiba, M.S., D.O.**, Resident Medical Officer, **Dr. S. Sujata, M.D.**, Head of Glaucoma Department and **Dr. D. Chandrasekhar, M.S., D.O.**, for their constant support and guidance.

I would like to thank **Dr.(CAPT) V.M. Loganathan, M.S, D.O.**, Professor, Director Community Ophthalmology, SRM Medical College & Hospital and Honorary Visiting Professor, Joseph Eye Hospital, Trichy for being my mentor and being a constant inspiration for students of Ophthalmology.

I would like to convey my gratitude to **Mr. R. Venkataraman**, Assistant Registrar for all his support and help. I would also like to thank **Mr. B.E. Rajakumar**, Librarian and **Mr. Daniel Prince**, Assistant Librarian for their support and help.

I will be failing in my duty if I do not express my indebtedness for cooperation to all my patients who participated in this study and made this dissertation possible.

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INTRODUCTION

Myopia or shortsightedness is defined as a type of refractive error in which parallel rays of light coming from infinity are focused in front of retina when accommodation is at rest

Myopia is divided into the following types, namely¹

- mild myopia: -1D to -3D;
- moderate myopia: -3D to -6D;
- high myopia: -6D to -12D;
- extreme myopia >12D.

Myopia could be **simple myopia** (axial, curvatural and index) or **pathological** myopia, which is characterized by increased axial length and degenerative changes in the eye.

Myopia can be corrected by non-surgical and surgical means. Modalities of non-surgical correction include the use of spectacles with a concave lens, and the wearing of contact lenses

Several modalities have been used for the surgical correction of myopia, namely:

- (1) radial keratotomy (RK), which is now only of historical importance;
- (2) photo -refractive keratotomy (PRK);

- (3) laser- in- situ keratomileusis (LASIK);
- (4) intrastromal corneal ring segments/ Intacs (ICSR);
- (5) clear lens extraction or refractive lens exchange;
- (6) implantable collamer lens (ICL) or phakic intraocular lenses (pIOLs).

The implantable collamer lens (ICL) represents a new category of IOLs that expands the range of keratorefractive surgery. This device allows patients with large refractive errors (myopia, hypermetropia) to achieve predictable outcomes, especially in those patients in whom laser refractive surgery is limited by the amount of corneal tissue that can be ablated and/or by the predictability of results.

Phakic IOLs are available as both foldable and non-foldable lenses and can be placed in the anterior or posterior chamber .Anterior chamber lenses are further divided into Angle supported or Iris clawed IOLs

The use of Phakic IOLs began in the 1950s in Europe with Strampelli², Dannheim³, Barraquer⁴ each separately attempting to design a better IOL Lack of modern IOL manufacturing capability and lack of microsurgical techniques resulted in a high incidence of complications such as corneal oedema, iritis, cataract and glaucoma.

In 1986-88, Baikoff presented his version of an anterior chamber angle fixated IOL⁵. The Baikoff ZB (Domilens,Lyon,France) was the first model to be distributed worldwide in 1986. This was replaced by ZB5M and ZB5MF lenses. In 1990s NuVita MA20 lens (Bausch And Lomb) was introduced. The Baikoff IOL is a single piece, biconcave anterior chamber lens based on Multiflex Kelman anterior chamber IOL. It is made of polymethylmethacrylate (PMMA) containing an ultraviolet blocker. The Kelman Duet (Tekia) is an angle-supported lens with independent PMMA haptics and frame, and a third-generation silicone optic. This lens comes in two separate pieces that are assembled inside the eye, and it has several advantages. The haptic can be exchanged leaving in the optic in the eye and vice versa.

Recently Alcon (Fortworth,TX,USA) introduced the Acrysof lens, a foldable single piece IOL made of soft acrylic. The complications of angle supported phakic lens included pupillary block, endothelial cell loss, haloes and glare, iritis, implant rotation and iris retraction with irregular pupil formation.

Iris supported phakic lenses, Artisan, were developed by Ophtec BV (Groninngen, Netherland) in 1991 and brought to USA as Verisyse phakic IOLs after US FDA approval in 2004. The Verisyse lens is a single piece lens made from PMMA with ultraviolet light absorbing material. It has a concave-convex optic incorporated into an 8.5mm elliptical plate lens and a slight anterior vault that creates space for aqueous flow and avoids contact with the crystalline lens. Artiflex is a flexible version of the Artisan iris claw lens, which has a special injector that allows it to be implanted through a

3.2mm incision. Like the Artisan, the iris claw haptics of the Artiflex are made from PMMA. The greatest risk of foldable anterior chamber lenses is the unfolding movement. The Artiflex lens is introduced into the anterior chamber with the specially designed spatula through a small incision. The withdrawal of the spatula automatically releases the IOL and allows it to unfold in the eye. The IOL is moved to center of the pupil and enclaved. Like Artisan, Artiflex also has the advantage of one size- fits- all. The toric version of Artisan and Artiflex need additional care and accuracy during implantation. The need continues to exist for a safe bio-compatible and easily fixated anterior chamber IOLs.

There are currently four models, 203 for correction of hyperopia, 204 and 206 for correction of myopia and toric model for correction of astigmatism 6mm. Of these only two models have been approved by FDA. The model 204 corrects myopia of -5D to -15D with optical zone of 6mm, model 206 corrects myopia of -5D to -20D with optical zone of 5mm.

Like angle supported phakic lenses, iris supported lenses too have similar risks after implantation like decreased endothelial cell count, elevation of intraocular pressure and chronic subclinical intraocular inflammation

The challenge in refractive surgery is presbyopia, which affects most people older than 40 years. The Bifocal refractive Phakic IOL (pIOL) is an anterior chamber angle supported lens marketed under the name of Newlife (IOL Tech) and Vivarte

(Cibavision). The optic is soft 28% hydrophilic acrylic and the haptic is PMMA and footplates are hydrophilic acrylic. The 5.5mm diameter optic is divided into center 1.50mm for distance, the intermediate 0.55mm for near and periphery 1.45mm for distance vision. The overall size of the lens varies from 12mm to 13mm. The IOL power ranges from -65D to +5D with +2.5D addition for near vision.

Posterior chamber IOLs have evolved in the past decade, and problems such as the risk of secondary cataract have been minimized. The Staar Surgical ICL is made of a collagen copolymer, a compound combining acrylic and porcine collagen (<0.1% collagen). Its refractive index is 1.45 at 35° C. The material is soft, elastic, and hydrophilic. The Visian ICL (STAAR Surgical) has reduced the risk of secondary cataract to 1%. Phakic ICL for myopia correction is available from -63 D to -23 D, optical diameter 5.50mm.

Phakic ICL for hyperopia correction is available from +3.0D to +21.5D, optical diameter 5.50mm. Toric ICL for myopia correction is available from -3.0D to -23D, Cylindrical power in half diopter increments from +1.0D to +6.0D

Implantation of posterior chamber IOLs in phakic eyes was reported by Fyodorov et al (1987). The original lens design was collar button type, with the optic located in the anterior chamber and the haptic behind the iris plane.

Later, Chiron-Adatomed modified this design to produce a silicon elastomer posterior chamber lens⁶. This lens design has been reported to have a high incidence of cataract formation after implantation

In 1993, Zaldivar et al began implanting a plate posterior chamber phakic IOL (Staar surgical implantable contact lens) (Zaldivar et al 1998). This lens design was modified from one that Fyodorov introduced in 1986-87, using a one piece silicon collar button phakic IOL with a 500-600 nm Teflon coat. Incorporation of a porcine collagen 2-Hydroxyethylmethacrylate (HEMA) copolymer into the lens material has improved the compatibility of this lens.

These improvements in ICL manufacture and modern microsurgical technique with improved knowledge of corneal endothelium and anterior segment structures led to greater success than with the original lens

This procedure not only gives satisfactory postoperative visual acuity but also improves quality of vision by overcoming limitations in night vision, loss of best corrected visual acuity (BCVA), visual aberration and diminished quality of vision. Visual outcome and patient satisfaction after phakic IOL (pIOL) surgery have been shown to be superior to that of laser in situ keratomileusis (LASIK) or photorefractive keratectomy (PRK) especially in high myopes as induced higher order aberrations are less and refractive results are more stable postoperatively⁷

Recently Phakic IOLs are available for correction of anisometropic amblyopias and presbyopia (bifocal lenses in anterior chamber)

The Food and Drug Administration of the USA (FDA) has approved 2 Phakic IOLs for myopia, namely the Posterior chamber Visian (STAAR) ICL Iris supported phakic intraocular lens (Verisyse)

Advantages of ICL implantation over other refractive procedures are excellent refractive accuracy, preservation of corneal asphericity (neither change in shape nor change in thickness) and preservation of accommodation, reversibility of the procedure and finally rapid visual recovery following surgery

This procedure not only gives satisfactory postoperative visual acuity but also improves quality of vision by overcoming limitations in night vision, loss of best corrected visual acuity (BCVA), visual aberration and diminished quality of vision⁸

AIM

To determine short term visual outcome and safety features following implantation of Implantable Collamer Lens (ICL) for correction of myopia.

REVIEW OF LITERATURE

Radial Keratotomy (RK)

First developed in 1898 and improved in 1960s. It is designed to correct myopia by making several small radial cuts on corneal surface that cause the cornea to flatten out in the centre. These incisions cause change in the way in which it focuses light on the retina. RK was most commonly used to treat patients with -1D to -4D of myopia.

Major advantages included , clear central optical zone of 3-4mm with no chances of central corneal haze, this procedure was less expensive than PRK and LASIK and postoperative visual recovery after this procedure was much earlier than PRK. Major disadvantages with this procedure were weakened cornea susceptible to rupture following trauma, uneven healing of cornea caused astigmatism and glare at night. One of the major drawbacks were also that stable, predictable results were hard to calculate.

Photorefractive keratotomy (PRK)

It is procedure of photoablation by Excimer laser which has been in use for treatment of myopia, hyperopia and astigmatism. Srinivasan, Barren and Trokel used Excimer laser for the first time in 1983 It gives good results from -2D to -6D of myopia

Indications

- ☞ Superficial scars or basement membrane dystrophy with myopia
- ☞ Cornea thinner than 500μ
- ☞ Crowded orbits with narrow palpebral fissure
- ☞ Glaucoma suspects

Advantages of PRK

- ☞ No weakening of globe unlike RK
- ☞ No night glare and diurnal variation in refraction unlike RK
- ☞ Results with an accuracy of 95% in achieving a $\pm 0.50D$ correction in patients with -2D to -6D of myopia

Drawbacks

- ☞ Corneal haze and regression
- ☞ Night glare and haloes
- ☞ Delayed epithelial healing
- ☞ Corneal ulcer formation
- ☞ Decentration of ablation zone

Laser in situ keratomileusis (LASIK)

It was first conceived in 1989 by Dr Pallikaris. FDA approved its use in 1999. It is the procedure of choice for myopia because of its definite advantages over PRK and RK. It can be used to correct upto -15D of myopia and upto -6D of astigmatism depending on the excimer laser platform used.

Advantages of LASIK over RK and PRK

- Minimal or no post operative pain
- Recovery of vision is very early as compared to PRK
- No or little risk of perforation during surgery and globe rupture due to trauma unlike RK
- No residual haze unlike PRK where subepithelial scarring may occur
- Can be effective in correcting upto -15D of myopia and upto -6D of astigmatism

Clear lens extraction or refractive lens exchange

Clear lens exchange had been advocated for myopia of -16D to -30D, especially in unilateral cases even before IOLs became popular. Treatment of myopia with clear lens extraction by phacoemulsification with appropriate IOL implantation (Fucala's operation) suggested that it is better to place a zero power IOL than no IOL, since it retards posterior capsule opacification (PCO) and reduces chances of retinal detachment in aphakic eyes. The minification effect of high concave glasses is removed

Indications

- Cornea is too thin, too flat, too steep and alternative refractive procedures are not feasible and
- Spectacles or contact lens are unacceptable
- Refractive error exceeds the limit of excimer laser and patient is more than 45yrs old

Drawbacks

- Loss of accommodation
- Higher chances of retinal detachment after lens extraction

Intra stromal corneal ring segments (ICRS) or Intacs Intra stromal corneal ring segments can treat low amounts of myopia by displacing the lamellar bundles and shortening the corneal arc length. These circular rings (two arc shaped segments) are made of polymethylmethacrylate (PMMA) are placed in the midperipheral corneal stroma in a lamellar channel. The two segments are of 150° of arc, available in five thicknesses (0.25,0.27,0.30,0.32 and 0.350mm) The thicker the segment, the greater the flattening of the cornea and the greater the reduction in myopia

There are several potential advantages of ring segments over other forms of refractive surgery such as reversibility of the procedure where rings can be explanted, rings can be replaced with ring segments of different thickness to titrate the refractive result, central corneal zone remains clear and aspheric because Intacs flatten the peripheral cornea more than the central cornea.

Certain disadvantages of intra stromal corneal ring segments make other refractive surgical procedures more popular. Specialized equipment and training is required to create the lamellar channels and to insert the ring segments, takes longer to perform than the LASIK procedure, patients experience discomfort and glare after the

surgery and this procedure corrects only low levels of myopia, it cannot correct hyperopia and astigmatism.

Complications with this procedure include anterior chamber perforation, microbial keratitis, implant expulsion, reduced corneal sensitivity, induced astigmatism, deep neovascularization at incision site

Sanders et al (2004) studied 3-year postoperative safety and efficacy outcomes with the Myopic Implantable Collamer Lens (ICL). In this study five hundred and twenty-six eyes of 294 patients with spherical equivalent between -3.0 and -20.0 diopters (D) of myopia had participated in the United States Food and Drug Administration clinical trial of ICL for myopia. The main outcome measures taken for this study were uncorrected visual acuity (VA), refraction, best spectacle-corrected VA (BSCVA), adverse events, operative and postoperative complications, lens opacity analysis, subjective satisfaction, and patient symptoms. At 3 years, 59.3% had 20/20 or better VA, and 94.7% had 20/40 or better uncorrected VA if BSCVA was 20/20 and patients were targeted for emmetropia; 67.5% of patients were within 0.5 D and 88.2% were within 1.0 D of predicted refraction. The mean improvement in BSCVA ranged between 0.5 and 0.6 lines. At 3 years postoperatively, 3 eyes (0.8%) decreased by ≥ 2 lines of BSCVA, in contrast to 40 eyes (10.8%) that improved by a similar amount. Contrast sensitivity improved postoperatively. Cumulative 3-year corneal endothelial cell loss was under 10%. Early largely asymptomatic, presumably surgically induced anterior subcapsular opacities (trace or greater) were seen in 14 eyes (2.7%), with only 2 being clinically

significant. Five eyes (0.9%) of 3 patients developed nuclear opacities of grade >2 at 2 to 3 years postoperatively. Three (0.6%) ICL removals with cataract extraction and IOL implantation have been performed. Only 0.6% reported dissatisfaction; 97.1% of patients reported they would choose ICL implantation again. Incidences of patient symptoms, glare, halos, double vision, night vision problems, and night driving difficulties decreased or remained unchanged after ICL surgery. Three-year results from this standardized, multicenter clinical investigation support the safety, efficacy, and predictability of ICL surgery to treat moderate to high myopic refractive errors.

Kamiya et al (2009) assessed the long-term clinical outcomes of implantation of a lens consisting of a biocompatible collagen copolymer (Visian implantable Collamer lens [ICL]; STAAR Surgical, Nidau, Switzerland) for moderate to high myopia. They evaluated 56 eyes of 34 patients with myopic refractive errors of -4.00 to -15.25 diopters (D) who underwent ICL implantation and routine postoperative examinations. Before and 1, 3, and 6 months and 1, 2, and 4 years after surgery, they assessed the safety, efficacy, predictability, stability, and adverse events of the surgery. Mean (SD) logMAR uncorrected and best spectacle-corrected visual acuities were -0.03 (0.23) and -0.21 (0.09), respectively, at 4 years after surgery. The mean (SD) safety and efficacy indexes were 1.19 (0.25) and 0.83 (0.29), respectively. At 4 years, 44 (79%) and 52 (93%) of the eyes were within 0.5 and 1.0 D, respectively, of the targeted correction. Mean (SD) manifest refraction changes of -0.24 (0.57) D occurred from 1 month to 4 years after surgery. No vision-threatening complications occurred during the observation period. Implantation of ICLs is safe and effective and provides predictable and stable refractive

results in the treatment of moderate to high myopia during a 4-year observation period, suggesting its viability as a surgical option for the treatment of such eyes.

Shen et al (2003) evaluated the efficacy, safety and stability of posterior chamber phakic IOL for correction of high myopia in 39 eyes of 20 patients with high myopia (between -11.75 and -25.75 diopters) had a posterior chamber PIOL (Staar ICL) implanted. During 6 - 48 months' follow-up, visual acuity, refraction, intraocular pressure (IOP), corneal reaction and space between crystal lens and intraocular lens (IOLs) were tested. Successful implantation was achieved in all patients. Visual acuity without correction greater than 0.5 was found in 34 eyes at 1 day and 3 months postoperatively. Thirty-five eyes maintained a low negative power of refraction (-1.42 ± 1.32 diopters), which did not prevent the patients from most of their daily activities. During 3 - 48 months' follow-up, refraction was stable and no cornea edema and glaucoma was found. Two eyes of one patient had corticosteroid glaucoma and another eye showed cataractogenesis under anterior capsular membrane. It was concluded that Posterior chamber PIOL implantation is predictable, safe, and effective in the correction of high myopia, and its indications should be carefully selected.

Lackner et al (2004) studied the incidence and progression of lens opacification after implantation of phakic posterior chamber intraocular lenses for myopia and its correlation with vaulting and endothelial cell density (ECD) in Department of Ophthalmology, University of Vienna Medical School, Vienna, Austria. An implantable contact lens (ICL V4, Staar Surgical Inc.) was inserted in 76 myopic eyes. Patients were

prospectively followed preoperatively and at 1, 3, 6, 12, 24, and 36 months. The uncorrected visual acuity and best corrected visual acuity (BCVA) were determined. Vaulting was measured optically with a Jaeger II pachymetry, and the crystalline lens was examined at the slitlamp for the presence and characteristics of opacification. Endothelial cell morphometry was performed by specular microscopy, and the ECD was calculated. Eyes in which lens opacification developed were followed for at least 12 months to determine the degree and course of visual impairment. Lens opacification occurred in 11 eyes (14.5%). Opacification was correlated with intraoperative trauma to the crystalline lens, age older than 50 years, and decreased ECD values throughout the observation period. Vaulting of the ICL did not correlate with the risk for lens opacification. After onset of lens opacification, 6 eyes (55%) had a stable BCVA within ± 0.5 lines and 5 eyes had progressive opacification, losing between 3.5 lines and 0.5 lines (mean 1.8 lines ± 1.1 [SD]). Three eyes (3.9%) in the progressive group had a 1- to 2-line loss of BCVA over preoperative values and subsequently had cataract surgery. Risk factors for lens opacification after implantation of the model V4 ICL included intraoperative trauma to the crystalline lens and older age. Decreased ECD in eyes with opacification suggests ongoing inflammation as a cause. Patients younger than 45 years may have a significantly lower incidence of opacification.

Donald Sanders et al(2007) Compared matched populations of LASIK and Visian Implantable Collamer Lens (ICL) cases in the correction of myopia between -3.00 and -7.88 diopters(D).One hundred sixty-four LASIK eyes with prospective data collected from a single center and 164 ICL eyes from the multicenter US ICL

Clinical Trial were compared in this observational non-randomized study.

The LASIK and ICL groups were well matched for age, gender, and mean level of preoperative spherical equivalent refraction. At 6 months, best spectacle-corrected visual acuity (BSCVA) -20/20 was 85% with LASIK and 95% with ICL ($P=.003$) compared to preoperative values of 93% and 88%, respectively ($P=.292$). Loss of ≥ 2 lines of BSCVA was significantly lower with the ICL at 1 week (0.6% vs 10%, $P=.001$) and 1 month (7% vs 0%, $P=.001$) with comparable outcomes at 6 months (0% vs 1%). At 6 months postoperatively, uncorrected visual acuity (UCVA) -20/15 (11% vs 25%, $P=.001$) and -20/20 (49% vs 63%, $P=.001$) was better in the ICL cases. Predictability within 0.50 D at 6 months for ICL cases was 85% (67% LASIK, $P=.001$); 97% of ICL cases were within 1.00 D (88% LASIK, $P=.002$). Refractive stability (± 0.50 D) between 1 and 6 months was 93% with ICL compared to only 82% with LASIK ($P=.006$).

The ICL performed better than LASIK in almost all measures of safety, efficacy, predictability, and stability in this matched population comparison, supporting the ICL as an effective alternative to existing refractive laser surgical treatments for the range of myopia studied.

Tsiklis NS et al (2007) compared the long-term results (9 years) of LASIK in one eye and phakic intraocular lens (implantable contact lens [ICL]) implantation in the fellow eye of the same patient. A patient with high myopia underwent LASIK with a MEL 60 excimer laser in one eye (spherical equivalent refraction -9.75 diopters [D], 5-

mm optical zone with no transition zone) and phakic intraocular lens (STAAR Collamer implantable contact lens [ICL]) implantation (spherical equivalent refraction -9.50 D) in the fellow eye. At 9 years postoperatively, the mean spherical equivalent refraction was -1.00 in the eye with the ICL and -1.75 D in the eye that underwent LASIK. During the first 6 postoperative months in the LASIK eye, refraction regressed, but remained stable during the remainder of follow-up. Uncorrected visual acuity was 20/25 in the eye with the ICL and 20/30 in the LASIK eye, whereas best spectacle-corrected visual acuity was 20/20 in both eyes. Less night vision problems (glare and halos) were experienced in the eye with the ICL compared to the LASIK eye. Although the patient initially preferred the LASIK procedure, at last follow-up 9 years postoperatively, increased overall satisfaction was reported for the eye with the ICL compared to the LASIK eye. Nine years after treatment of high myopia with the ICL and LASIK in the same patient, better quality of vision, stability, and satisfaction score were achieved in the eye with the ICL compared to the eye that had undergone LASIK. No long-term sight-threatening complications were found during followup.

Igarashi et al(2009) Compared postoperative visual function after implantable collamer lens (ICL; STAAR Surgical, Nidau, Switzerland) implantation and after wavefront-guided laser in situ keratomileusis (WFG-LASIK) in eyes with high myopia. Retrospective, observational case study. We investigated 46 eyes of 33 patients undergoing ICL implantation and 47 eyes of 29 patients undergoing WFG-LASIK (Technolas217z; Bausch & Lomb, Rochester, New York, USA) for the correction of high myopia (manifest spherical equivalent \leq -6 diopters). Ocular higher-order

aberrations (HOA) and contrast sensitivity (CS) function were measured by Hartmann-Shack aberrometry (KR-9000; Topcon, Tokyo, Japan) and a CS unit (VCTS-6500; Vistech Consultants Inc, Dayton, Ohio, USA) before and 3 months after surgery, respectively. From the CS, the area under the log CS function (AULCSF) was calculated.

For a 4-mm pupil, the changes in ocular coma-like aberrations, spherical-like aberrations, and total HOAs after ICL implantation were significantly less than those after WFG-LASIK ($P < .001$, Mann-Whitney U test). The postoperative AULCSF was significantly increased after ICL implantation ($P < .001$), whereas after WFG-LASIK, it was significantly decreased ($P < .001$). ICL implantation induces significantly fewer ocular HOAs than WFG-LASIK. Moreover, CS was improved significantly after ICL implantation, but deteriorated after WFG-LASIK in eyes with high myopia. Thus, in the correction of high myopia, ICL implantation seems to be superior in visual performance to WFG-LASIK, suggesting that it may be a better surgical option for the treatment of such eyes.

M EK et al studied to find out the refractive and visual results of posterior chamber lens implantation into phakic eyes for correction of high myopia and the reliability of the method. The Russian designed, negative silicone intraocular contact lenses (ICLs) were implanted into 54 eyes of 30 patients having high myopia by the same surgeon .

Under general anaesthesia in all eyes a negative ICLs were implanted on the crystalline lens through a 6 mm corneal incision at the steepest axis and dilated pupil. A decrease in refractive error was achieved in all eyes. Twenty-four of the eyes (44.4 %) were within ± 1.00 diopter (D), and all eyes were within ± 2.00 D of the attempted correction. The mean best-corrected visual acuity (BCVA) was 4.25/10 preoperatively and 7.80/10 postoperatively ($p < .001$). No serious complication was seen except for ICL damage by the lens holder in 2 eyes (3.7 %) peroperatively and a transient intraocular pressure (IOP) increase in 9 eyes (16.6 %) in the postoperative period. The clinical and functional follow-up of the ICL implantation indicates that this method of high degree myopia correction is a good alternative when photorefractive keratectomy, LASIK and radial keratotomy are unavailable or unsuitable. A long term follow-up of the results of the negative ICL implantation has not been made yet. Thus the clinical and functional results of this technique indicate the need for further improvement of this method for myopic correction

Ahmed M Emarah et al (2010) compare the outcomes of clear lens extraction and collamer lens implantation in high myopia. Myopic patients younger than 40 years old with more than 12 diopters of myopia or who were not fit for laser-assisted *in situ* keratomileusis were included. Group 1 comprised patients undergoing clear lens extraction and Group 2 patients received the Visian implantable collamer lens. Outcome and complications were evaluated.

Postoperative best corrected visual acuity was -0.61 ± 0.18 in Group 1 and 0.79 ± 0.16 in Group 2. In Group 1, 71.4% achieved a postoperative uncorrected visual acuity better than the preoperative best corrected visual acuity, while only 51.8% patients achieved this in Group 2. Intraocular pressure decreased by 12.55% in Group 1, and increased by 15.11% in Group 2. Corneal endothelial cell density decreased by 4.47% in Group 1 and decreased by 5.67% in Group 2. Posterior capsule opacification occurred in Group 1. In Group 2, lens opacification occurred in 11.11%, significant pigment dispersion in 3.7%, and pupillary block glaucoma in 3.7%.

Clear lens extraction presents less of a financial load up front, and less likelihood of the need for a secondary intervention in the future. Clear lens extraction is a more viable solution in developing countries with limited financial resources.

METHODS AND MATERIALS

Patients with moderate to high myopia ($>-3.0\text{D}$ to -19.0D) who underwent implantable collamer lens (ICL) implantation during the period from June 2009 to June 2010 at Institute of Ophthalmology, Joseph Eye Hospital, Trichy formed the study population.

The data collection and analysis was carried out during the period from July 2009 to October 2010 which included 25 patients (40 eyes) who underwent implantation for various indications such as moderate to high myopia and compound myopic astigmatism. This was approved by the Institutional Ethics Committee.

Design

Prospective, non randomized study

Main outcome measures

Post operative visual acuity, number of eyes gaining or losing one or more lines (snellen visual acuity chart), predictability, efficacy index (Mean postoperative UCVA/ Mean preoperative BCVA), safety index (Mean postoperative BCVA/ Mean preoperative BCVA) and complications if any.

ICL Power Calculation

ICL power calculation was performed by the manufacturer (Visian ICL; STAAR) using an online modified vertex formula on entering the necessary data i.e Refractive error, eye selected RE or LE for procedure, Keratometry K1 and K2 with axis, ACD(endothelium to lens) and White to White measurement of the cornea. Each lens is custom made. In all eyes, emmetropia was selected as the target refraction to reduce the preoperative refractive errors as much as possible

Individuals were enrolled in the study if the following features were present:

- (a) Moderate to high myopia (spherical equivalent of $>-3.0\text{D}$ to -19.0D)
- (b) Anterior chamber depth (from corneal endothelium to lens) more than 2.8 mm.
- (c) A round pupil with a open angle of anterior chamber
- (d) A normal intra ocular pressure (10 mmHg- 20 mmHg)

Individuals were excluded from enrollment if any of the following conditions were present:

- (a) inflammation of the anterior and posterior segment
- (b) chronic keratitis
- (c) corneal dystrophy
- (d) iris atrophy or rubeosis
- (e) aniridia

- (f) cataract
- (g) vitreous pathology
- (h) retinal disease
- (i) microphthalmos
- (j) nanophthalmos
- (k) glaucoma
- (l) previous intra ocular surgery
- (m) intra ocular pressure more than 20 mmHg

Each individual enrolled in the study underwent the following investigations:

- (a) accurate manifest refraction
- (b) anterior chamber depth measurement using IOL master
- (c) corneal topography
- (d) ultrasound pachymetry for measurement of central corneal thickness
- (e) white-white measurement of cornea
- (f) detailed slit lamp examination
- (g) fundus examination

A standard proforma (see Appendix) was used to collect data regarding the patients including name, age, sex, diagnosis, visual acuity (uncorrected and best corrected visual acuity both preoperatively and postoperatively) .

Two weeks before the surgery, Nd: YAG laser iridotomy were performed. On the day of

surgery the combination of mydriatic topical medication (e.g., tropicamide 1% with phenylephrine 2.5%) was applied serially, beginning 1 hour before surgery; in addition flurbiprofen drops were applied three times preoperatively.

The anaesthesia method was based on patient and surgeon preferences and peribulbar anaesthesia was used for all patients in this study

Surgical procedure

An entry with MVR blade was made at the 6 o'clock position and aqueous humour was replaced by a viscoelastic. A temporal corneal tunnel (length- 3.2mm) was created using a keratome (3.2mm) and viscoelastic was injected to form the anterior chamber.

The implant can be inserted by one of the following two different techniques in which front loading injector technique was used in all patients in this study

(a) With an injector as described by Arne and Hoang-Xuan (2001). Here IOL was positioned in the lens insertion cartridge under direct visualization with the operating microscope. The injector tip was placed in the tunnel and the lens is injected into the anterior chamber. As the IOL unfolded slowly, its progression was controlled, ensuring proper orientation.

(b) With a forceps , the tip of which was introduced into the entrance of the tunnel.

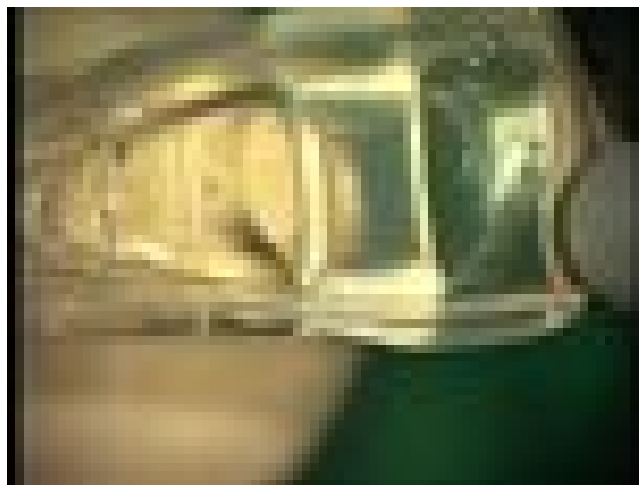
Another Macpherson forceps held in the other hand to grasp the implant. The first forceps was opened, to regrasp the IOL a little further and to push it slowly. By repeating these maneuvers with the forceps, the IOL was able to move in the tunnel and to unfold in a controlled manner. It was ensured that the tip of the forceps did not enter the anterior chamber to avoid contact with the crystalline lens.

While the IOL was unfolding, its proper orientation was checked. Then each footplate was placed one after the other beneath the iris with a specially designed, flat, nonpolished, manipulator, without placing pressure on the crystalline lens. Care was taken to avoid touching the optic of the ICL in the middle, as this is the thinnest part. Then the OVD material was removed with gentle irrigation-aspiration and intracameral pilocarpine was injected. Subconjunctival injection of steroid-antibiotic was given. Acetazolamide was given in the postoperative period to decrease the intraocular pressure.

ICL HELD IN CORRECT POSITION WITH STAAR
FOAM TIP APPLICATOR



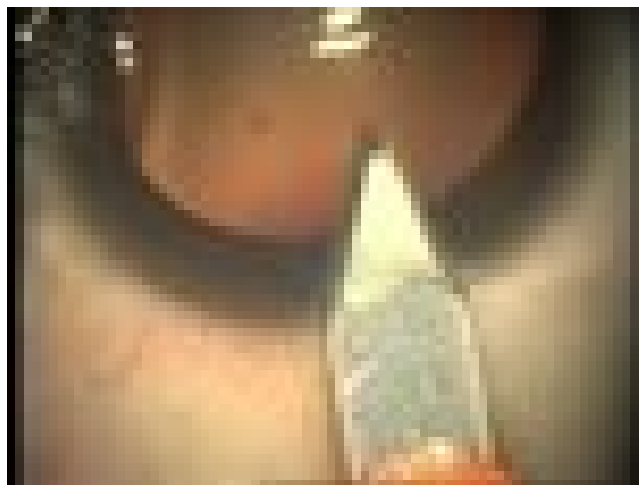
ICL BEING LOADED IN THE INJECTOR
CARTRIDGE



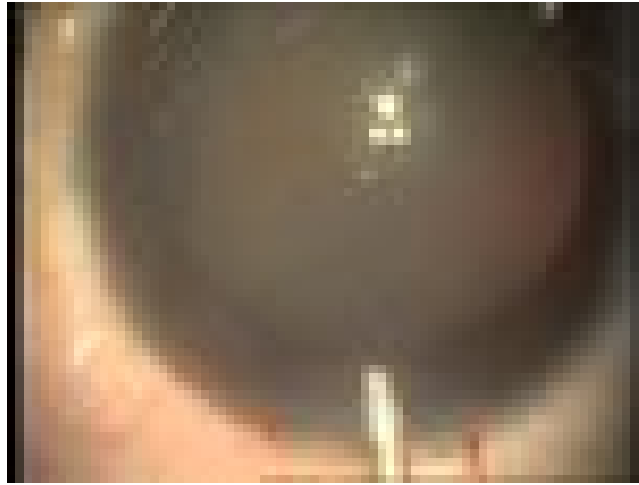
ICL BEING PULLED WITH FRONT LOADING
FORCEPS INTO THE INJECTOR



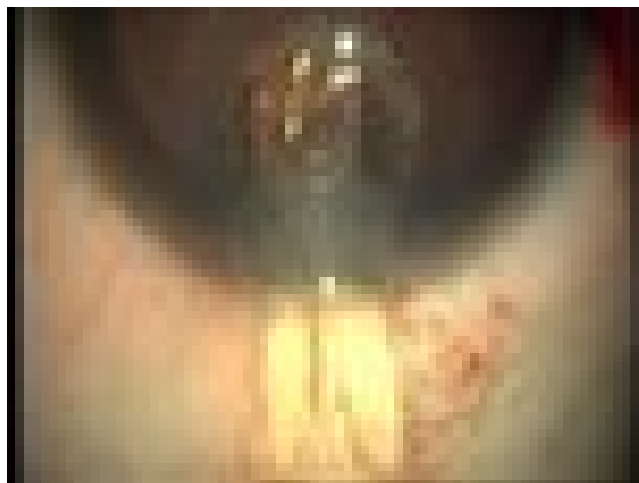
TEMPORAL CLEAR CORNEAL INCISION BEING
MADE



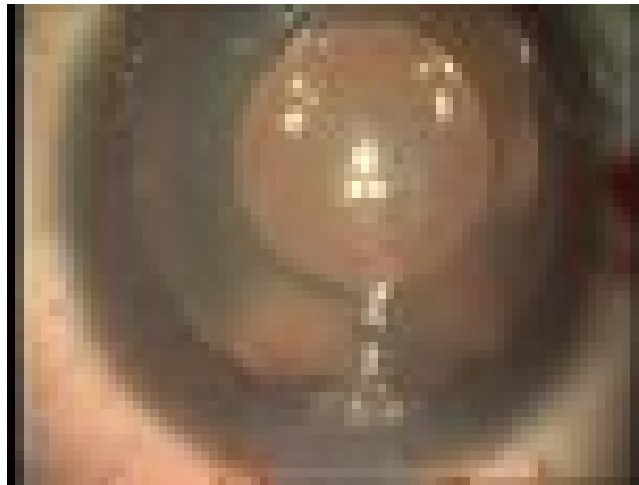
VISCOELASTIC MATERIAL BEING INJECTED
INTO THE ANTERIOR CHAMBER



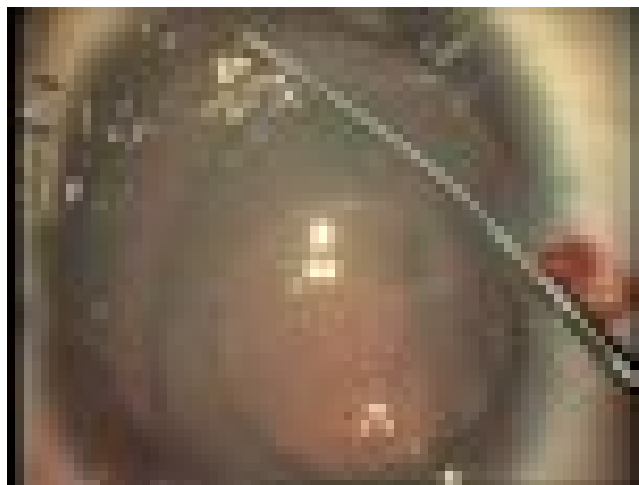
ICL BEING INJECTED THROUGH THE CARTRIDGE



ICL INITIALLY PLACED IN THE ANTERIOR
CHAMBER



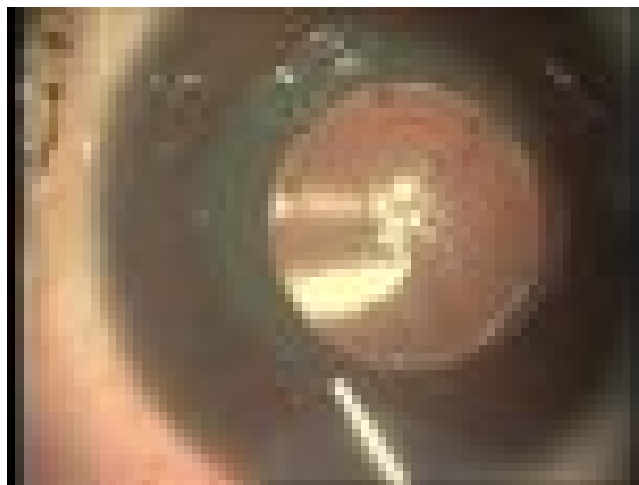
DISTAL FOOTPLATE TUCKED BENEATH THE IRIS
WITH VUKICH'S MANIPULATOR THROUGH
SIDEPORT



PROXIMAL FOOTPLATE TUCKED BENEATH THE
IRIS WITH VUKICH'S MANIPULATOR THROUGH
MAIN INCISION



VISCOELASTIC BEING WASHED OUT AFTER ICL
IS PROPERLY POSITIONED IN POSTERIOR
CHAMBER



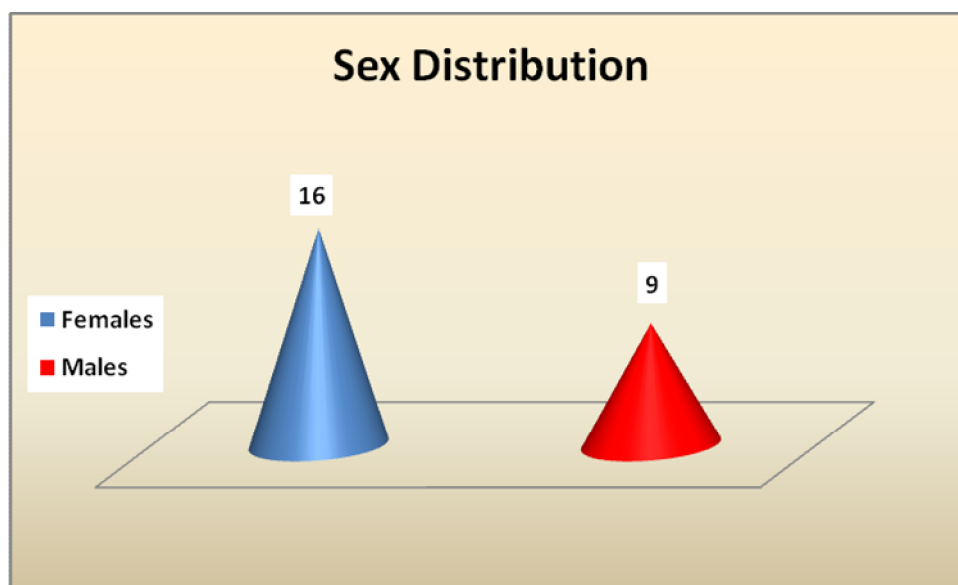
RESULTS

Twenty five patients were enrolled in this study , of whom 16 (64%) were females and nine (36%) were males (Table-1, Figure-1).

TABLE 1 Sex Distribution

Sex Distribution	Females	Males
No. of Patients	16	9

FIGURE – 1



Age distribution

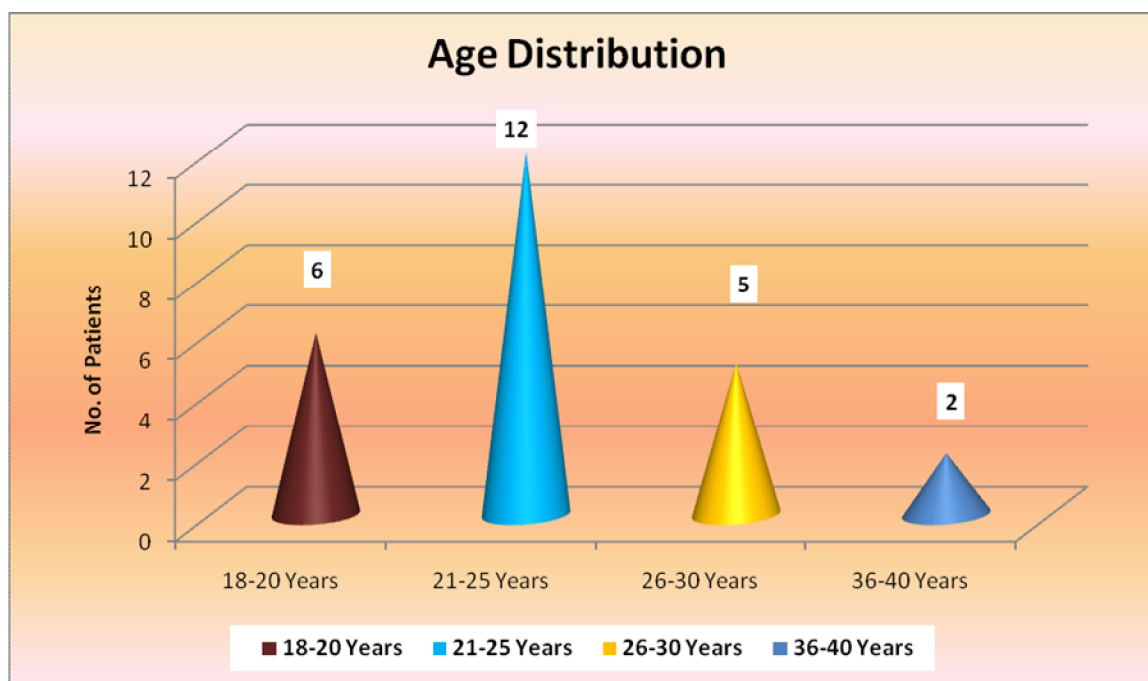
Six (24%) patients were in the 18 -20 year age group, 12 (48%) were in the 21-25 year age group, five (20%) were in the 26-30 year age group and two (8%) were in the 36-40 year age group (Table- 2, Figure -2); there was no patient in the 31-35 year age group.

The mean age of the patients was 24.04 (± 5.5) years.

TABLE 2 - Age Distribution

Age Distribution	18-20 Years	21-25 Years	26-30 Years	31-35 Years	36-40 Years
No. of Patients	6	12	5	0	2

FIGURE – 2



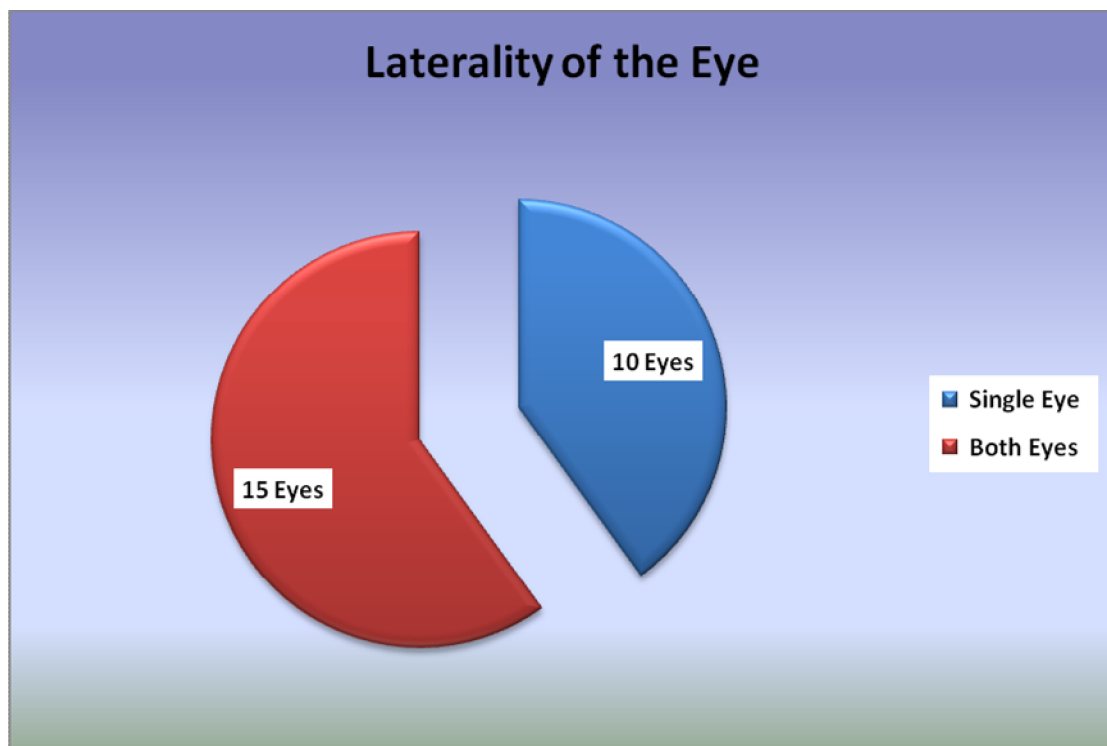
Laterality

In this study, there were 10 patients with an ICL implanted in one eye and 15 patients with ICLs implanted in both eyes, that is, a total of 25 patients and 40 eyes[right eye 20(50%);left eye 20(50%)] (Table-3, Figure-3).

TABLE 3 - Laterality

Laterality	Single Eye	Both Eyes
No. of Patients	10	15

FIGURE – 3



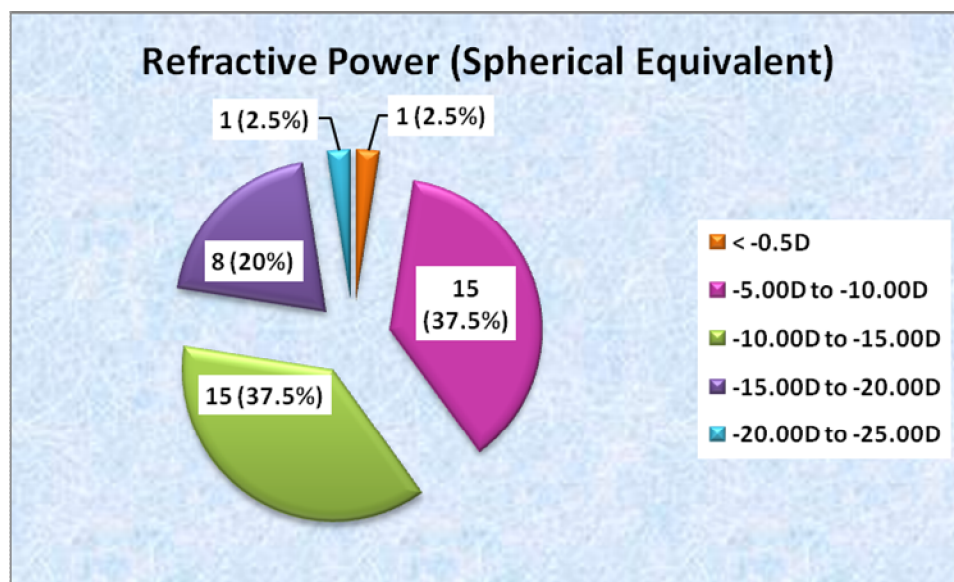
Pre-operative refractive power

One (2.5%) of 40 eyes had a refractive power less than -5.0 D, 15 (37.5%) had a refractive power from -5.00 D to -10.00 D, 15 (37.5%) had a refractive power from -10.00 D to -15.00 D, eight (20%) had a refractive power from -15.00 D to -20.00 D and only one (2.5%) of 40 eyes had a refractive power from -20.00 D to -25.00 D (Table-4, Figure -4) The mean spherical equivalent prior to surgery was -12.15 D (\pm 4.52D)

TABLE 4 - Refractive power (Spherical Equivalent)

Refractive power	< -0.5D	-5.00D to -10.00D	-10.00D to -15.00D	-15.00D to -20.00D	-20.00D to -25.00D
No. of eyes	1 (2.5%)	15 (37.5%)	15 (37.5%)	8 (20%)	1 (2.5%)

FIGURE– 4



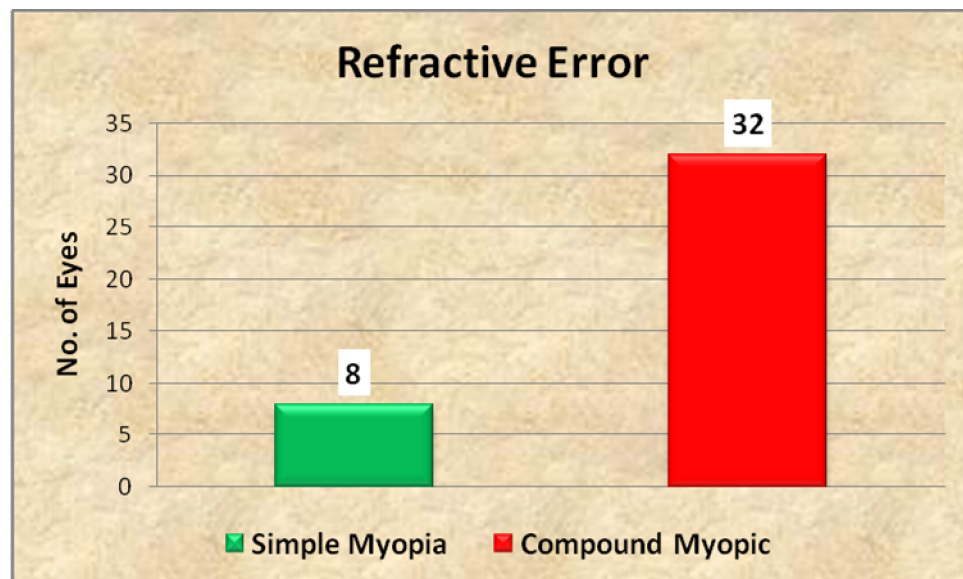
Type of refractive error

Eight (20%) of the 40 eyes presented with simple myopia while 32 (80%) of the 40 eyes presented with compound myopic astigmatism (80%) (Table-5, Figure-5). Interestingly, the right eye was involved in seven of the eight eyes with simple myopia and only a single left eye had simple myopia.

TABLE 5 - Refractive Error

Refractive Error	Simple Myopia	Compound Myopic
No. of eyes	8	32

FIGURE – 5



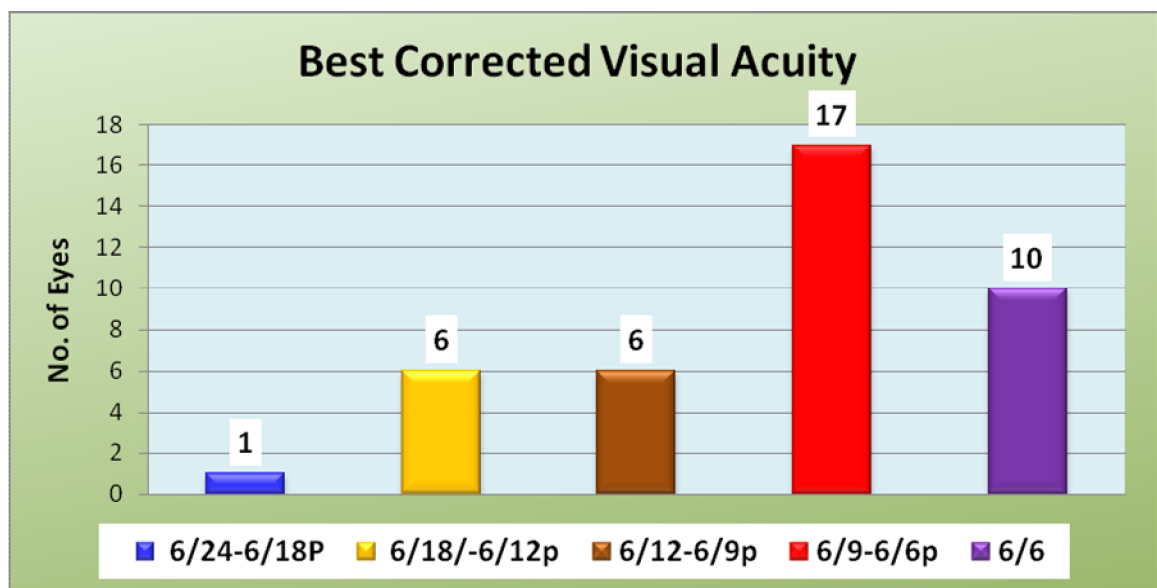
Pre-operative best corrected visual acuity (BCVA)

The preoperative BCVA was between 6/24 and 6/18p in one(2.5%) of the 40 eyes, between 6/18 and 6/12p in six(15%) of the 40 eyes, between 6/12 and 6/9p in six(15%) of the 40 eyes and between 6/9 and 6/6p in 17(42.5%) of the 40 eyes; the preoperative BCVA was 6/6 in 10(25%) of the 40 eyes (Table-6, Figure -6). The preoperative mean decimal visual acuity was $0.73(\pm 0.22)$ (approximately between 6/9 and 6/6).

TABLE 6 - Pre Operative Best Corrected Visual Acuity(BCVA)

Pre Operative (BCVA)	6/24-6/18P	6/18/-6/12p	6/12-6/9p	6/9-6/6p	6/6
No. of eyes	1	6	6	17	10

FIGURE – 6



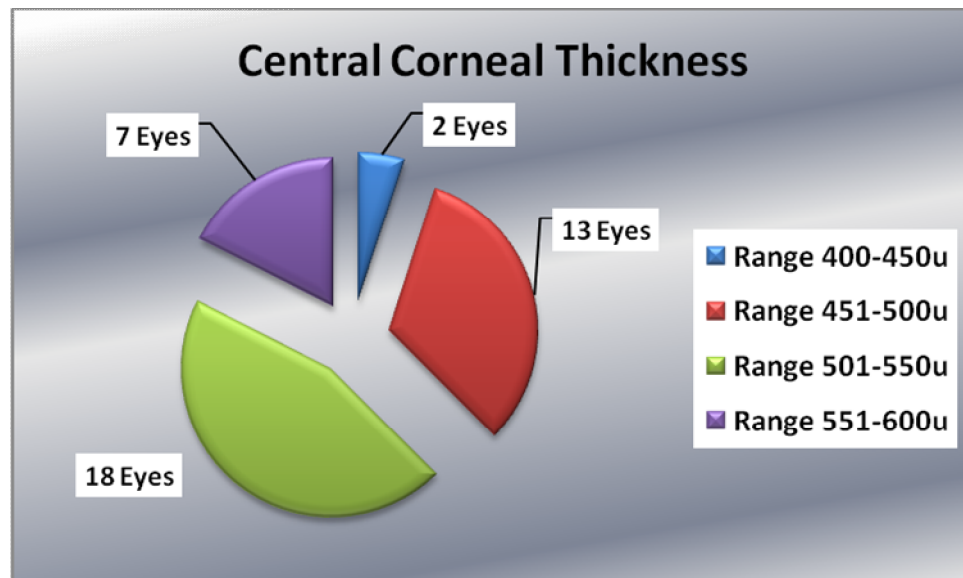
Central corneal thickness(CCT)

Two (5%) of the 40 eyes had a CCT from 400 to 450 μ , 13(32.5%) had a CCT from 451 to 500 μ , 18 (45%) had a CCT from 501 to 550 μ and seven (17.5%) of the 40 eyes had a CCT from 551 to 600 μ (Table-7, Figure-7). The mean preoperative CCT was 511.6(\pm 36.8) μ .

TABLE 7 - Central corneal thickness in Microns

Central corneal thickness in Microns	Range 400-450u	Range 451-500u	Range 501-550u	Range 551-600u
No. of eyes	2	13	18	7

FIGURE – 7



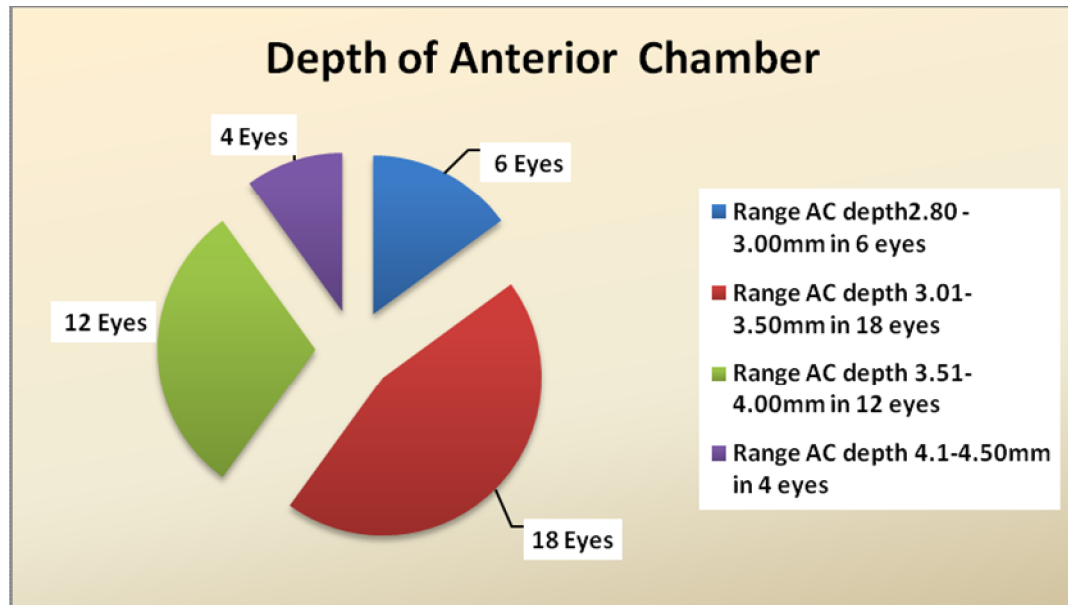
Anterior chamber (AC) depth

The depth of the AC was 2.8 to 3.0 mm in six(15%) of the 40 eyes, 3.01 to 3.5 mm in 18(45%), 3.51 to 4.0 mm in 12(30%) and 4.1 to 4.5 mm in 4(10%) of the 40 eyes(Table- 8, Figure -8). The mean preoperative AC depth was 3.43(\pm 0.36) mm.

TABLE 8 - Anterior Chamber Depth in millimeters

Anterior Chamber depth in millimeters	Range AC depth 2.80 -3.00mm	Range AC depth 3.01-3.50mm,	Range AC depth 3.51-4.00mm,	Range AC depth 4.1-4.50mm,
No. of eyes	6	18	12	4

FIGURE – 8



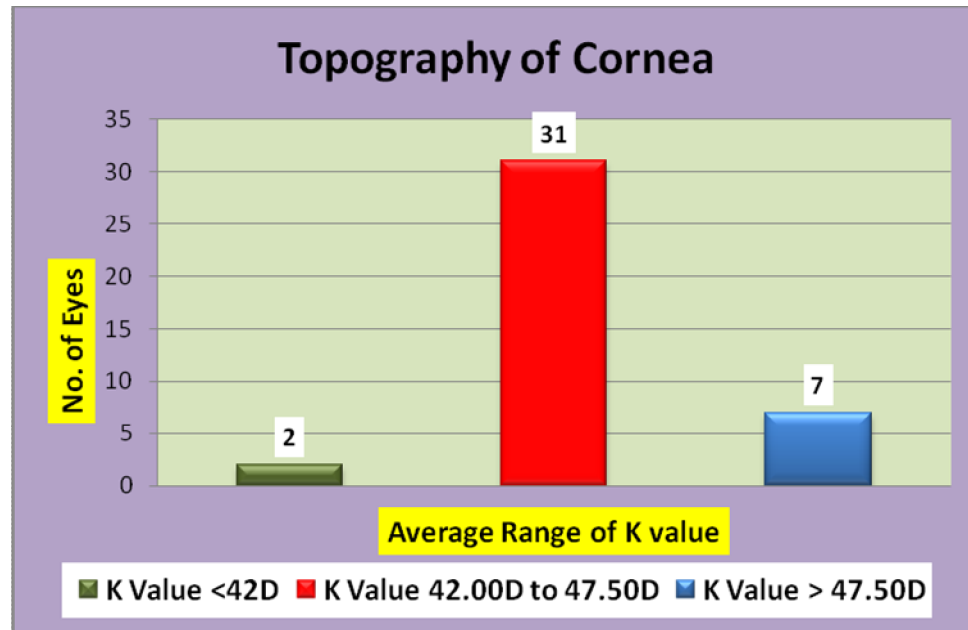
Corneal topography

Two(5%) of the 40 eyes exhibited an average K- value of <42 D, 31(77.5%) exhibited an average K- value of 42.00 D to 47.50 D and seven (17.5%) of the 40 eyes exhibited an average K- value of > 47.50D (Table-9, figure -9)

TABLE 9 - Corneal Topography

Corneal Topography	K Value <42D	K Value 42.00D to 47.50D	K Value > 47.50D
No. of eyes	2	31	7

FIGURE – 9



Post operative refractive error

At four weeks following surgery, the mean spherical equivalent error was $-0.24D (\pm 0.12D)$. The difference between the preoperative mean spherical equivalent and the postoperative mean spherical equivalent values was statistically significant [unpaired t -test = 16.673 (degree of freedom [d.f.] = 78); 2-tailed P value < 0.0001].

Postoperative visual acuity

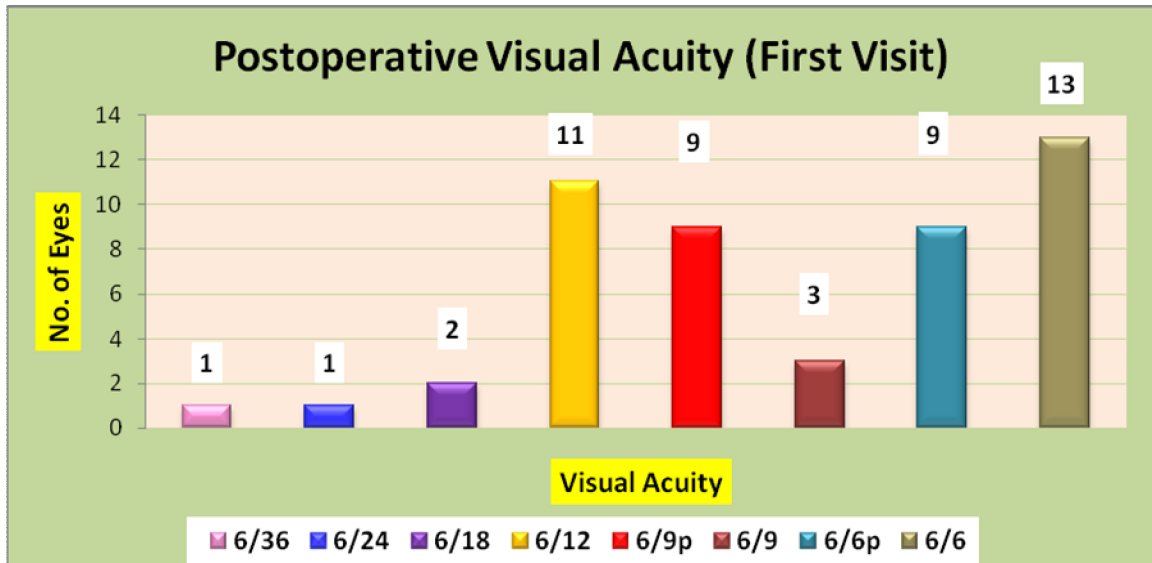
a) At the first post operative visit, the visual acuity was 6/36 in one (2.5%) of the 40 eyes, 6/24 in one (2.5%), 6/18 in two (5%) and 6/12 in two (5%) of the 40 eyes, 6/9 in nine (22.5%) and 6/6 in thirteen (32.5%) of the 40 eyes. (Table- 10, Figure- 10).

Preoperatively, 14(35%) of 40 eyes had a visual acuity of 6/6p or 6/6 while postoperatively(1st visit) , 22(55%) of 40 eyes had a visual acuity of 6/6p or 6/6; this difference was not statistically significant [chi-square with Yates's correction=-2.475 (d.f.=1); P= 0.1157].

TABLE 10 - Postoperative visual acuity first visit

Postoperative visual acuity first visit	6/36	6/24	6/18	6/12	6/9p	6/9	6/6p	6/6
No. of eyes	1	1	2	11	9	3	9	13

FIGURE – 10



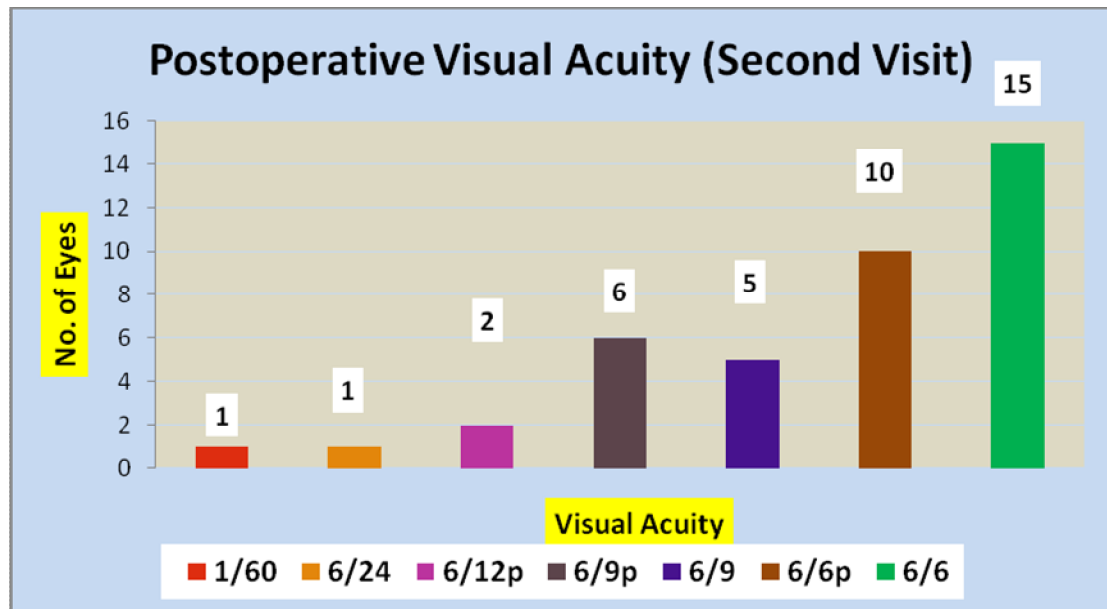
b) At the second postoperative visit, the visual acuity was 1/60 in one(2.5%) of the 40 eyes, 6/24 in one(2.5%) and 6/12 in two (5%) of the 40 eyes, 6/9p in six(15%) and 6/9 in five(12.5%) of the 40 eyes, 6/6p in ten(25%) and 6/6 in fifteen(37.5%) of the 40 eyes (Table- 11, figure- 11).

Preoperatively, 14(35%) of 40 eyes had visual acuity of 6/6p or 6/6 while postoperatively(2nd visit) , 25(62.5%) of 40 eyes had a visual acuity of 6/6p or 6/6; this difference was statistically significant [Chi-square with Yates's correction= 5.003 (d.f.= 1); P= 0.0253].

TABLE 11 - Postoperative visual acuity second visit

Postoperative visual acuity second visit	1/60	6/24	6/12p	6/9p	6/9	6/6p	6/6
No. of eyes	1	1	2	6	5	10	15

FIGURE – 11



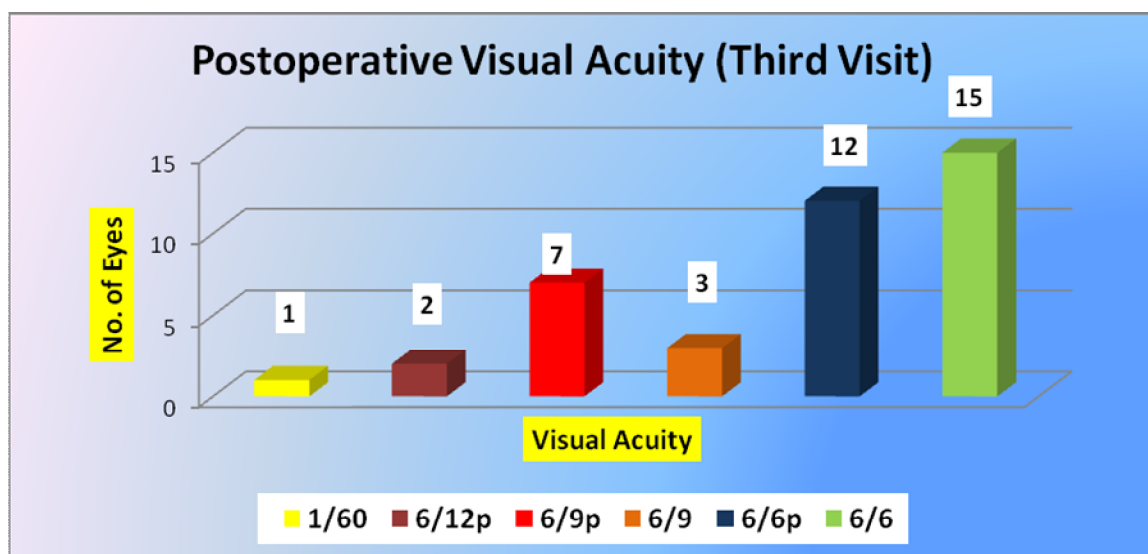
c) At the third postoperative visit, the visual acuity was 1/60 in one (2.5%) of the 40 eyes, 6/12p in two(5%) of the 40 eyes, 6/9p in seven(17.5%) and 6/9 in three(7.5%) of the 40 eyes , 6/6p in 12(30%) and 6/6 in 15(37.5%)of the 40 eyes(Table- 12, Figure- 12).

Preoperatively, 14(35%) of 40 eyes had visual acuity of 6/6p or 6/6 while postoperatively(3rd visit) , 27(67.5%) of 40 eyes had a visual acuity of 6/6p or 6/6; this difference was statistically significant [Chi-square with Yates's correction = 7.205 (d.f.=1); P= 0.0073]

TABLE 12 - Postoperative visual acuity third visit

Postoperative visual acuity third visit	1/60	6/12p	6/9p	6/9	6/6p	6/6
No. of eyes	1	2	7	3	12	15

FIGURE – 12

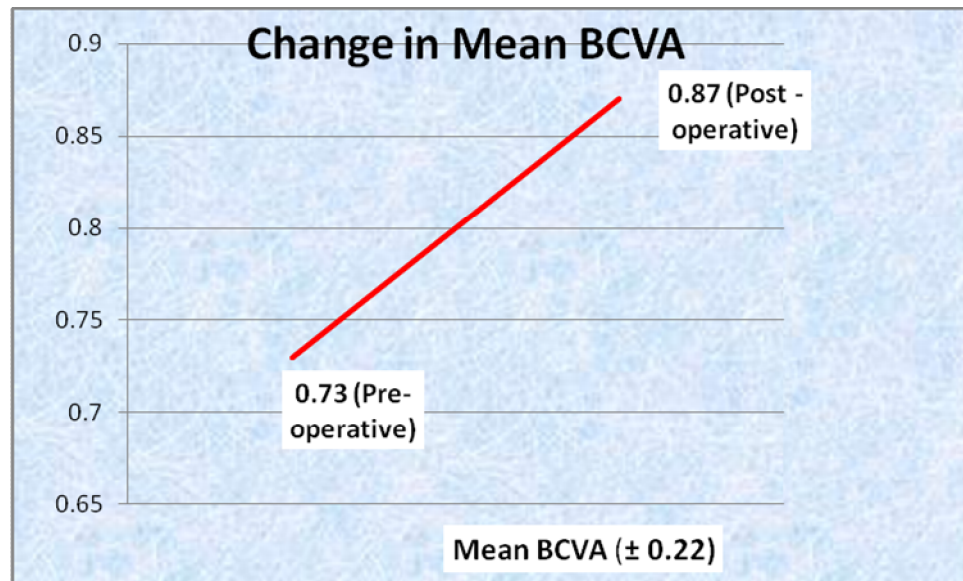


d) The postoperative mean best corrected decimal visual acuity was 0.87(± 0.22) (approximately between 6/9 and 6/6), while the preoperative mean decimal visual acuity was 0.73(± 0.22); this difference was statistically significant ($P < 0.0001$). (Table- 13, figure- 13).

TABLE 13 - Change in Mean BCVA

Pre-operative Mean BCVA	Post-operative Mean BCVA
0.73	0.87

FIGURE – 13



Gain or loss of vision in the study eyes following implantation of pIOL

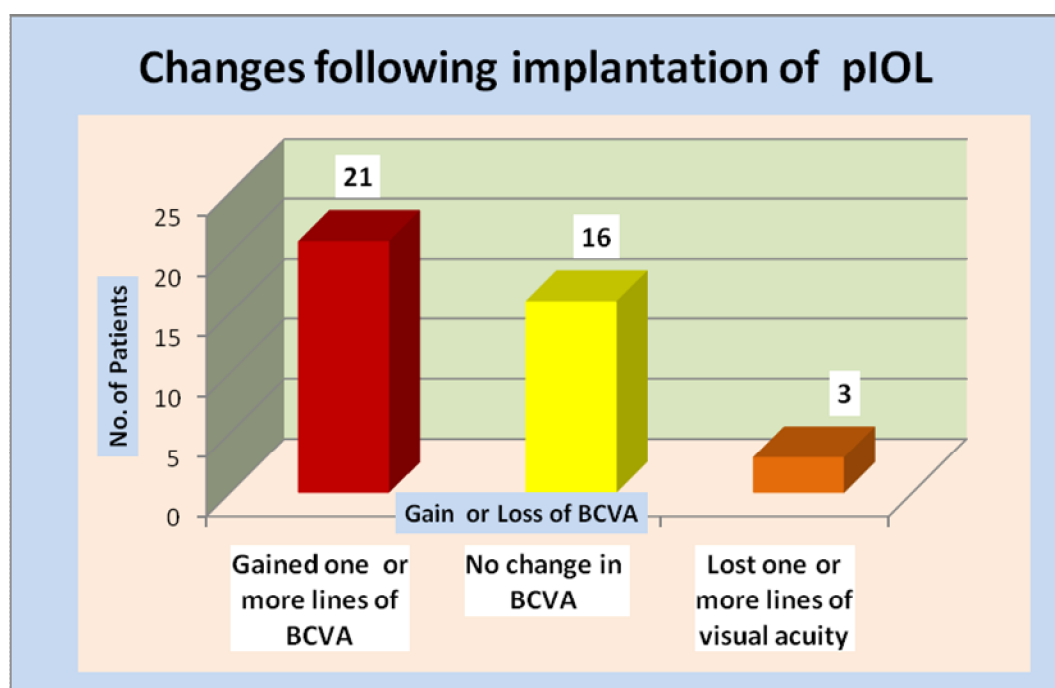
a) Twenty- one (52.5%) of the 40 eyes gained one or more lines of BCVA, 16 (40%) had no change in BCVA and three (7.5%) of the 40 eyes actually lost one or more lines of visual acuity. (Table- 14, figure- 14).

TABLE 14 - Gain or loss of vision in the study following implantation of pIOL

Gained one or more lines of BCVA	No change in BCVA	Lost one or more lines of visual
----------------------------------	-------------------	----------------------------------

		acuity
21	16	3

FIGURE – 14



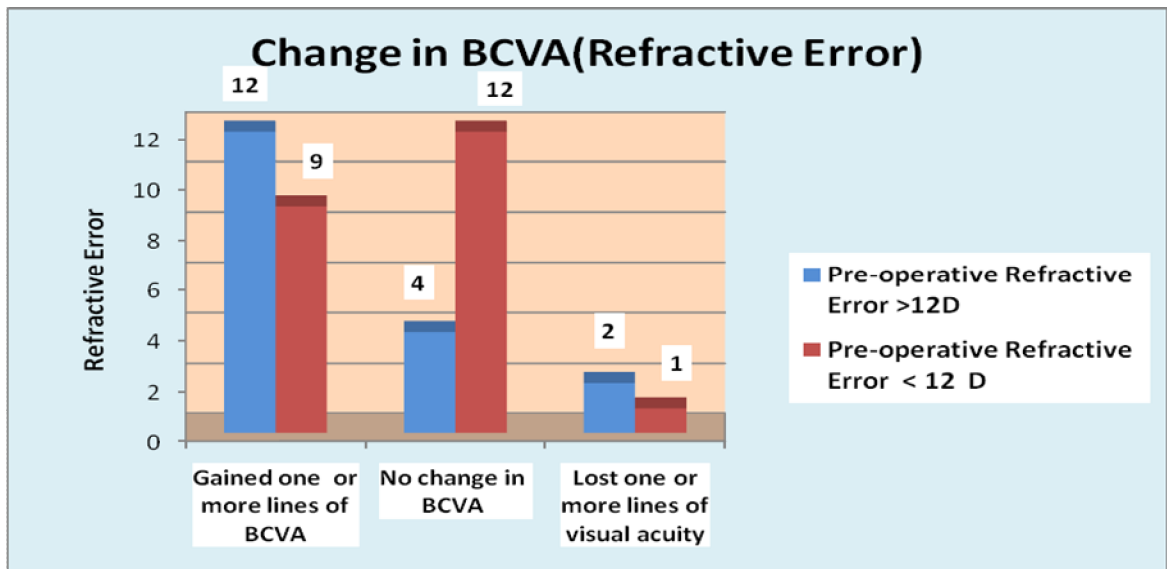
b) Eighteen (45 %) of the 40 eyes had a preoperative refractive error >12 D (extreme myopia) while 22 (55%) of the 40 eyes had a preoperative refractive error ≤ 12 D. Of the 18 eyes with a preoperative error > 12 D, 12 gained one or more lines of BCVA, four had no change in BCVA and 2 lost one or more lines of visual acuity following surgery while of the 22 eyes with preoperative error ≤ 12 D, nine gained one or more lines of BCVA, 12 had no change in BCVA and one eye lost one or more lines of visual acuity following surgery (Table- 15, figure- 15) ; this difference approached , but did not

achieve statistical significance (chi-square with Yates's correction = 4.56 [d.f.=2] ; P= 0.07).

TABLE 15 - Preoperative Refractive Error >12D and <12D

	Gained one or more lines of BCVA	No change in BCVA	Lost one or more lines of visual acuity
Pre-operative Refractive Error >12D	12	4	2
Pre-operative Refractive Error \leq 12 D	9	12	1

FIGURE – 15



Efficacy index

The efficacy index (ratio of mean postoperative UCVA to mean preoperative BCVA) was calculated to be 1.18, indicating that the postoperative mean uncorrected visual acuity was better than the preoperative mean best corrected visual acuity.

Safety index

The safety index (ratio of mean postoperative BCVA to mean preoperative

BCVA) was calculated to be 1.23; indicating that the postoperative mean best corrected visual acuity was better than the preoperative mean best corrected visual acuity.

Predictability

This was calculated to be 100%

Complications

a) Five (12.5%) of the 40 eyes had a transient rise in intraocular pressure (IOP), which was controlled by topical medication.

b) Only one patient developed a severe rise in IOP, in one of the two eyes operated; in view of the intractable glaucoma, the ICL had to be replaced. In this patient, the preoperative spherical equivalent (SE) was 21D and post operative visual acuity was 1/60.

c) No other complications were observed during the study.

DISCUSSION

Myopia is a common cause of visual disability throughout the world. The World Health Organization has grouped myopia and uncorrected refractive error among the leading causes of blindness and vision impairment in the world (<http://www.who.int/blind-ness/causes/priority/en/index5.html>, accessed 1st December 2010). Recent studies have confirmed the existence of a large burden of uncorrected refractive errors, although the interventions required are significantly cost effective, and have an important impact on economic development and quality of life. Severe refractive errors have been estimated to account for about 5 million blind people (<http://www.who.int/blind-ness/causes/priority/en/index5.html>; accessed 1st December 2010). Hence, any study on modalities of correction (treatment) of these priority eye diseases is of great relevance.

There are two main types of surgical correction for moderate to high myopia, namely, excimer laser and phakic intraocular lenses (pIOLs). Basically, in excimer laser refractive surgery for myopia, some portion of the corneal stroma is removed to reduce the refractive power of the cornea and therein to bring the image of a viewed object into focus onto the retina rather than in front of it. Conversely, pIOLs used for the treatment of myopia work by diverging light rays so that the image of a viewed object is brought into focus onto the retina rather than in front of it.

Surgical correction of astigmatism by IOL implantation has advanced rapidly in the past few years. Toric IOL implantation is a reversible procedure that can correct astigmatism and spherical refractive errors while preserving the corneal contour. The use of pIOLs is a small but emerging area in refractive surgery. For patients with high myopia and inadequate vision with glasses or intolerance to contact lenses, options are limited. Corneal refractive surgery such as laser in-situ keratomileusis (LASIK) can safely and reliably correct myopia up to approximately ± 12 D, but at higher diopters, it achieves less satisfactory results along with increased risks of corneal ectasia. In addition, IOL implantation with lensectomy yields loss of accommodation, along with increased risks of retinal detachment in high myopes. The advent of pIOLs offers the possibility of refractive correction without the loss of accommodation.

Fyodorov developed the first posterior chamber pIOL in 1986. Interestingly, Bozkurt et al.(2010) have recently described a patient who had received such a pIOL (Fyodorov IOL) 18 years previously to correct myopia; after a long lapse in the follow-up, the patient presented with a reduced endothelial cell count but without any sign of cataract⁹. The patient was totally satisfied even after 18 years. Borzkut et al. (2010) believed that theirs was the first report of a long follow-up of a patient implanted with a first-generation PC pIOL.

Posterior chamber pIOLs came to the market as the Chiron-Adatomed Lens (Chiron- Adatomed GmbH, Munich, Germany), and the Visian Implantable Collamer Lens (Staar

Surgical, Monrovia, CA). The most recent design of the Visian lens (V4 ICL) was approved By the United States (US) Food and Drug Administration (FDA) in December 2005. It is made of collamer, a hydrophilic porcine collagen/hydroxyethyl methacrylate (HEMA) copolymer, with an ultraviolet-absorbing chromophore. The Visian ICL features a plate haptic design with central convex/concave optical zone and incorporates a forward vault to minimize contact of ICL with the capsule of the normal crystalline lens. This ICL features an optic diameter with an overall diameter that varies with the dioptric power, the smallest optic/overall diameter being 4.9mm/12.1mm and largest optic/overall diameter being 5.8mm/13.7mm. The lenses are capable of being folded and inserted into the posterior chamber (behind the iris and in front of anterior capsule of crystalline lens) through an incision of 3.5mm or less. The lens functions as a refractive element to optically reduce moderate to high myopia. The Staar ICL for myopia correction is the first phakic IOL approved in the US by FDA in 2004. It is the first IOL of any kind to be approved for patients younger than 60 yrs and a refractive procedure correcting myopia ranging from -3D to -15D and with astigmatism ≤ 2.5 D. It also reduces myopia ranging from greater than -15D to -20D.

Another commercially available posterior chamber pIOL (not yet FDA approved) is the Phakic Refractive Lens or PRL (Ciba Vision, Duluth, GA, USA; Medennium Inc., Irvine, CA, USA), which is made of hydrophilic silicone.

Barsam and Allan (2010) reviewed the effects of excimer laser refractive surgery versus phakic IOLs for the correction of moderate to high myopia¹⁰. They searched the Cochrane Central Register of Controlled Trials (CENTRAL), as well as MEDLINE,

EMBASE and Latin American and Caribbean Literature on Health Sciences (LILACS); randomised controlled trials (RCTs) comparing excimer laser refractive surgery and phakic IOLs for the correction of myopia greater than 6.0 D spherical equivalent were included. The review included three RCTs with a total of 228 eyes. The range of myopia in the patients included was -6.0 D to -20.0 D of myopia with up to 4.0 D of myopic astigmatism. The percentage of eyes with uncorrected visual acuity (UCVA) of 20/20 or better at 12 months postoperative was not significantly different between the two groups. Phakic IOL surgery was deemed to be safer than excimer laser surgical correction for moderate to high myopia as it resulted in significantly lower loss of best spectacle corrected visual acuity (BSCVA) at 12 months postoperatively. However, there was a low risk of developing early cataract with phakic IOLs. Phakic IOL surgery appeared to result in better contrast sensitivity than excimer laser correction for moderate to high myopia. Phakic IOL surgery also scored more highly on patient satisfaction/preference questionnaires. The authors concluded that the results of their review suggested that pIOLs are safer than excimer laser surgical correction for moderate to high myopia in the range of -6.0 to -20.0 D, and that pIOLs are preferred by patients. However, these authors were also of the opinion that while pIOLs might be accepted in clinical practice for higher levels of myopia (greater than or equal to 7.0 D of myopic spherical equivalent with or without astigmatism), it might also be worth considering pIOL treatment over excimer laser correction for more moderate levels of myopia (less than or equal to 7.0 D of myopic spherical equivalent with or without astigmatism). There have been similar studies in the past where ICL implantation was considered in eyes with both moderate to high as well as low myopia (Zaldivar R et al .1998; Sanders DR et al 1998; Jimé'nez-

Alfaro I et al 2001 etc).¹¹⁻²⁰. Sanders and Vukich reported that ICL had advantages over Lasik , not only in eyes with moderate to high myopia but also with low myopia²¹⁻²³

In view of the observations made by Barsam and Allan in their review, it is surprising that there are just a handful of documented investigations in the literature pertaining to studies done in India. A search of the Pub Med database using the key words `phakic intraocular lenses; studies in India generated just four papers (Titiyal et al. 2010; Senthil et al. 2006; Bhattacharjee et al. 2006; Fechner et al. 1998).²⁴⁻²⁷ Of these, only one paper (Senthil et al. 2006) is relevant to the subject of the present dissertation, posterior chamber pIOLs; moreover, that study dealt with Artisan pIOLs. Hence, the investigation on which this present dissertation is based appears to be unique in a number of respects.

The purpose of this study, conducted in a tertiary eye care hospital in southern India, was to assess the visual outcomes, safety, efficacy and predictability of ICL implantation for correction of moderate to high myopia.

In the present study, there were 25 patients (sixteen females and nine males; mean age of 24.04 ± 5.5 years). Forty eyes of these 25 patients presented with the spherical equivalent (SE) between -5.50 and -21.0 dioptres (D) and only one eye with SE ≤ 5.0 D. There were eight eyes with simple myopia (20%) and 32 eyes with compound myopic astigmatism (80%) The right eye was involved in seven of the eight eyes with simple myopia and only a single left eye had simple myopia. Implantable collamer lens (ICL) lens was inserted in myopic eyes; there were 10 patients with ICL implanted in one

eye and 15 patients with ICL implanted in both the eyes. Post-operative follow-up occurred at one, two and four weeks.

In the present study, the mean decimal visual acuity preoperatively was $0.73(\pm 0.22)$ (approximately between 6/9 and 6/6) and the postoperative mean best corrected decimal visual acuity was $0.87(\pm 0.22)$ (approximately between 6/9 and 6/6); this difference was highly statistically significant.

Twenty-one (52.5%) of the 40 eyes gained one or more lines of BCVA. Comparison of post-operative visual results in which patients with preoperative myopia $\leq 12D$ and those with preoperative myopia $>12D$ (extreme myopia) revealed that 12 (67%) of 18 eyes in the extreme myopia group gained one or more lines of BCVA as compared to nine (41 %) of 22 eyes in patients with myopia $\leq 12 D$. Although the difference appears sizable, in statistical terms, the difference only approached statistical significance ($P= 0.07$) without achieving it. However, it should be noted that gain in one or more lines and improvement in visual acuity in patients with extreme myopia is significant because the minification effect of glasses is reduced as the ICL implantation moves the focus close to the nodal point of the eye, leading to visual improvement; in comparison, in patients with $< 12D$, vision remains stable and may not achieve significant improvements as in patients with extreme myopia.

Alonso et al. (2010a) assessed the predictability, efficacy, safety, and stability of a collagen copolymer toric pIOL (Intraocular Collamer Lens) implantation to correct moderate to high myopic astigmatism in an ophthalmological institute in Spain.²⁸ The

uncorrected and corrected distance visual acuities, refraction, pIOL vault, and adverse events were evaluated over 12 months. Preoperatively, the mean sphere in the 55 eyes was -4.65 D (standard deviation [SD] 3.02) (range -0.50 to -12.50 D) and the mean cylinder, -3.03 (SD 0.79) D (range -1.25 to -4.00 D). At 12 months, the mean Snellen decimal UCVA was 0.80 (SD 0.20) and the mean BCVA was 0.85 (SD 0.18); 62.0% of eyes had a BCVA of 20/20. More than 50.0% of eyes gained one or more lines of BCVA. The treatment was highly predictable for spherical equivalent and astigmatic. Of the eyes, 94.5% were within 0.50 D of the attempted SE and all were within 1.00 D. The efficacy index was 0.95 at 3 months and 1.08 at 1 year. The authors concluded that the UCVA and BCVA with toric pIOLs were good and highly stable over 12 months, confirming that the procedure was safe, predictable, and effective for correction of moderate to high astigmatism. When comparing the results of the present investigation with those reported by Alonso et al. (2010 a), it is interesting to note that in the present investigation, 52.5 % of patients gained more than one line of BCVA and the safety index and efficacy index were both more than 1, while in the study by Alonso et al. (2010 a), more than 50.0% of eyes gained one or more lines of BCVA, and the efficacy index was less than 1 at 3 months and only exceeded 1 after 12 months.

In another recent study, Alfonso and co-investigators (2010b) assessed the safety, efficacy, stability, and predictability after implantation of a toric intraocular copolymer (Collamer) lens (pIOL) to correct high myopic astigmatism in 15 eyes of 12 patients (9 women) in an ophthalmological institute in Spain.²⁹ Preoperatively, the mean manifest spherical refraction was -1.98 D (SD 1.32) (range -0.50 to -5.50 D) and the mean

refractive cylinder was -4.85 (SD 0.83) D (range -6.50 to -4.00 D). At 12 months, the mean refractive cylinder was -0.55 (SD 0.52) D (range -1.50 to 0.00 D), with 93.3% of eyes having less than 1.00 D of cylinder. The mean spherical equivalent was -0.31 (SD 0.42) (range -1.00 to 0.75 D), with more than 70% of eyes within 0.50 D of the target. For the astigmatic components, 93.3% of eyes were within 1.00 D of J0 and all eyes were within 1.00 D of J45. The mean UCVA was 0.70 (SD 0.20) and the mean BCVA was 0.83 (SD 0.12). The overall efficacy index was 0.90. Postoperatively, all eyes had unchanged UCVA or gained one or more lines. The authors concluded that refractive outcomes and improvement in UCVA and BCVA were rapidly achieved and remained fairly consistent throughout the follow-up period, supporting the use of toric pIOLs in eyes with high astigmatism.

Several adverse events have been reported to occur with the use of posterior chamber pIOLs; these range from mild corneal oedema and iritis to more severe complications such as clinically significant endothelial cell loss, pigment dispersion syndrome, pigmentary glaucoma and pupillary block, significant cataract, glaucoma, macular/subretinal haemorrhage and retinal detachment (Guell et al. 2010).³⁰

However, in the present study, few adverse events were noted. Five (12.5%) of the 40 eyes exhibited a transient rise in IOP which was controlled by topical medication. Only one patient developed a marked rise in IOP in one of the two eyes operated; this patient with intractable glaucoma required replacement of ICL, his preoperative spherical

equivalent (SE) was 21D and post operative visual acuity was 1/60. No other complications were observed during the course of this study.

Yousef et al. (2010) in the USA assessed the histopathology of anterior subcapsular cataract associated with the use of the Visian ICL using light microscopy after pIOL explantation and cataract surgery.³¹ Pathology specimens related to explanted pIOLs were reviewed and preoperative and postoperative patient data collected. The anterior lens capsules and explanted pIOLs were examined. Four eyes (three patients) had pIOL explantation for low vault and anterior subcapsular cataract. The explanted pIOLs were the shorter length models (3, 12.1 mm; 1, 12.6 mm). Anterior segment optical coherence tomography (AS-OCT) confirmed the low pIOL vault before explantation in 2 eyes. Histopathology of the anterior subcapsular cataract showed fibrous metaplasia with a variable number of lens epithelial cell (LEC) layers attached to the inner surface of the anterior capsulorhexis specimens. Light microscopy of the explanted pIOLs showed no pigment on 1 lens, mild pigment deposition on 1 haptic, and pigment deposition throughout the anterior surface of 2 pIOLs.. The authors concluded that anterior subcapsular cataract associated with the pIOLs was caused by low vaulting (confirmed on AS-OCT) and consequent fibrous metaplasia of the anterior LECs.

In the present study, none of the eyes appeared to have developed a cataract. However, the short follow-up period of the present investigation may account for the absence of such a finding. USFDA Clinical trial of ICL in moderate to high myopia showed complications (between 1 and 36 months) occurring in Ö 1% of cases and

included retinal detachments in 0.6%, glaucoma in 0.4%, clinically significant surgically induced anterior subcapsular cataract in 0.4% and macular/subretinal haemorrhage in 0.2% cases. There were no cases of persistent corneal oedema, hypopyon, hyphema, macular oedema and endophthalmitis.

The clinical trials involved in the FDA approval process for the Visian ICL showed it could provide a safe, reversible method of correcting moderate to high myopia which is similar to this study. However, one of the risks associated with posterior chamber PIOLs, but less so with anterior chamber PIOLs, is the development of cataracts. There was no incidence of lens opacification observed in this study.

Sanders²⁰⁰⁷ report examined the development of cataracts 5 years after surgery in the Visian Lens FDA trial. Their study enrolled 291 patients (526 eyes) with myopia ranging between -3 and -20.0 D. At 12 months postoperatively, UCVA was 20/40 or better in 92.5% and 20/20 or better in 60.1%. The most common adverse event was anterior subcapsular opacities. Sanders²⁰⁰⁷ most recent study reported the development of anterior subcapsular opacities during a minimum 5-year follow-up period. He found that anterior subcapsular opacities occurred in 5.9% of eyes at 7+ years. They generally occurred early, with 58% being seen in the first year, 68% in the first 2 years, and 74% in the first 3 years. However, only 1.3% progressed to clinically significant cataract, and those were usually in very high myopes and older patients.

A recent meta analysis by Chen et al in 2008 involved a systemic literature review to determine the incidence of and predisposing factor for cataract after PIOL implantation

Of 6338 eyes, 4.35% were noted to have new-onset or preexisting progressive cataract.

The study included angle supported, iris-supported, and posterior chamber PIOLs. The incidence of cataract formation was 1.29%, 1.11%, and 9.60%, respectively. Amongst the new-onset cataracts, nuclear sclerosing was the predominant type in the anterior chamber group (60.0%) and iris-fixed group (50.0%), whereas anterior subcapsular was the predominant type in the posterior chamber group (90.58%). These results suggest that cataract formation is most likely to occur after posterior chamber PIOL implantation. In the posterior chamber PIOL group, early cataract formation was related to surgical trauma and late cataract formation was related to IOL-crystalline lens contact.

A limitation of the present investigation is that the duration of the study was relatively short (one year); a longer follow up is needed to assess final visual outcome and safety of the procedure in the population of patients from which the study patients were chosen.

Another limitation of this study is that endothelial cell counts were not measured.

CONCLUSION

The present study was undertaken to assess the efficacy of the implantable collamer lens (ICL) in correction of myopia (including moderate to high myopia) in a southern Indian population, an aspect on which there appears to be limited verifiable data. The results of the present study suggest that phakic intraocular lens implantation for the correction of myopia seems to be an effective and predictable procedure for moderate to high myopia. However, a longer follow up is required to assess the effect of age-related changes, such as an increase in the thickness of the lens.

SUMMARY

Myopia and uncorrected refractive error are among the leading causes of blindness and vision impairment in the world, hence studies on modalities to correct these priority eye diseases are of great relevance. There are two main types of surgical correction for moderate to high myopia, namely excimer laser and phakic intraocular lenses (pIOLs).. The use of pIOLs is a small but emerging area in refractive surgery. A recent evidence-based review suggested that phakic IOLs are safer than excimer laser surgical correction for moderate to high myopia in the range of -6.0 to -20.0 D, and that pIOLs are preferred by patients. However, there are just a handful of documented investigations in the literature pertaining to studies on pIOLs done in India. The present investigation is believed to be the first in southern India to investigate the efficacy of the implantable collamer lens (ICL) for the correction of myopia.

Twenty five patients were enrolled in this study , of whom 16 (64%) were females and nine (36%) were males. The mean age of the patients was 24.04 (± 5.5) years. There were 10 patients with an ICL implanted in one eye and 15 patients with ICLs implanted in both eyes, that is, a total of 25 patients and 40 eyes[right eye 20(50%);left eye 20(50%)] were evaluated in the study.

In the 40 eyes, the mean spherical equivalent prior to surgery was -12.15 D (± 4.52 D). Eight (20%) of the 40 eyes presented with simple myopia while 32 (80%) of the 40 eyes presented with compound myopic astigmatism (80%). In the 40 eyes, the preoperative mean decimal visual acuity was 0.73(± 0.22) (approximately between 6/9

and 6/6). The mean preoperative central corneal thickness was $511.6(\pm 36.8)\mu$ and the mean preoperative anterior chamber depth was $3.43(\pm 0.36)$ mm. Two(5%) of the 40 eyes exhibited an average K- value of <42 D, 31(77.5%) exhibited an average K- value of 42.00 D to 47.50 D and seven (17.5%) of the 40 eyes exhibited an average K- value of > 47.50 D.

At four weeks following surgery, the mean spherical equivalent error was -0.24D (± 0.12 D). The difference between the preoperative mean spherical equivalent and the post-operative mean spherical equivalent values was statistically significant [$P < 0.0001$].

Preoperatively, 14(35%) of 40 eyes had a visual acuity of 6/6p or 6/6. At the first post-operative visit, 22(55%) of 40 eyes had a visual acuity of 6/6p or 6/6, at the second post-operative visit 25(62.5%) of 40 eyes had a visual acuity of 6/6p or 6/6 while at the third visit, 27(67.5%) of 40 eyes had a visual acuity of 6/6p or 6/6. The difference between the proportion of eyes with visual acuity of 6/6p or 6/6 pre-operatively and that at the first post-operative visit was not statistically significant. However, the difference between the proportion of eyes with visual acuity of 6/6p or 6/6 pre-operatively and that at the second post-operative visit was statistically significant ($P=0.0253$). Similarly, the difference between the proportion of eyes with visual acuity of 6/6p or 6/6 pre-operatively and that at the third post-operative visit was statistically significant ($P= 0.0073$).

The postoperative mean best corrected decimal visual acuity was $0.87(\pm 0.22)$ (approximately between 6/9 and 6/6), while the preoperative mean decimal visual acuity was $0.73(\pm 0.22)$; this difference was statistically significant ($P < 0.0001$).

Twenty- one (52.5%) of the 40 eyes gained one or more lines of best corrected visual acuity (BCVA), 16 (40%) had no change in BCVA and three (7.5%) of the 40 eyes actually lost one or more lines of visual acuity.

Eighteen (45 %) of the 40 eyes had a preoperative refractive error > 12 D (extreme myopia) while 22 (55%) of the 40 eyes had a preoperative refractive error ≤ 12 D. Of the 18 eyes with a preoperative error > 12 D, 12 gained one or more lines of BCVA, four had no change in BCVA and two lost one or more lines of visual acuity following surgery while of the 22 eyes with preoperative error ≤ 12 D, nine gained one or more lines of BCVA, 12 had no change in BCVA and one eye lost one or more lines of visual acuity following surgery; this difference approached but did not achieve, statistical significance ($P = 0.07$)

The efficacy index (ratio of mean postoperative UCVA to mean preoperative BCVA) was calculated to be 1.18, indicating that the postoperative mean uncorrected visual acuity was better than the preoperative mean best corrected visual acuity.

The safety index (ratio of mean postoperative BCVA to mean preoperative

BCVA) was calculated to be 1.23; indicating that the postoperative mean best corrected visual acuity was better than the preoperative mean best corrected visual acuity.

The predictability was calculated to be 100%

With regard to complications, five (12.5%) of the 40 eyes had a transient rise in intraocular pressure (IOP), which was controlled by topical medication. Only one patient developed a severe rise in IOP, in one of the two eyes operated; in view of the intractable glaucoma, the ICL had to be replaced. In this patient, the preoperative spherical equivalent (SE) was 21 D and post operative visual acuity was 1/60. No other complications were observed during the study.

A limitation of the present study is that the duration was relatively short (one year); a longer follow- up is necessary to assess final visual outcome and safety of the procedure. An additional limitation of this study is that endothelial cell counts were not measured

The results of the present study suggest that phakic intraocular lens implantation for the correction of myopia seems to be an effective and predictable procedure for patients who present with moderate to high myopia. However, a longer follow up is required to assess the effect of age-related changes, such as an increase in the thickness of the lens.

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PROFORMA

M.R.NO:

DATE:

AGE/SEX:

HISTORY:

OCCUPATION:

COMPLAINTS:

OCULAR EXAMINATION:

RE

LE

VISUAL ACUITY:

DISTANCE:

NEAR:

BEST CORRECTED VISUAL ACUITY:

SLIT LAMP EXAMINATION

FUNDUS EXAMINATION:

DIAGNOSIS:

INTRAOCULAR PRESSURE

CORNEAL TOPOGRAPHY:

ANTERIOR CHAMBER DEPTH:

CENTRAL CORNEAL THICKNESS:

WHITE- WHITE DIAMETER:

POSTOPERATIVE VISUAL ACUITY:

COMPLICATIONS:

S.NO	M.R.NO	AGE	SEX	EYE	UNAIDED V/A	SUBJECTIVE CORRECTION	SPHERICAL EQUIVALENT	BCVA	FUNDUS	DIAGNOSIS	CCT (μ)	CORNEAL TOPOGRAPHY (D)		AC DEPTH (mm)	WHITE-WHITE (mm)		POST-OP V/A		COMPLICATION	FOLLOW UP PERIOD
												K1	K2			AFTER 1 WEEK	AFTER 2 WEEKS	AFTER 4 WEEKS		
1	721875	18	F	LE	1/60.	RE-14.50/-1.75x170	15.37	6/9.	Disc partially tilted	Compound Myopic Astigmatism	538	45.87-76	44.00-166	3.85	11.75	6/6p	6/6P.	6/6P.	NIL	9 months
2	707494	22	M	RE	5/60.	RE -9.75 Dsph	9.75	6/6.	Normal	Simple Myopia	479	41.87-180	41.87-90	3.41	11.25	6/6.	6/6.	6/6.	NIL	1 year
3	628481	22	F	LE	3/60.	LE -11.75/-1.25x160	12.37	6/12p	Peripapillary Atrophy	Compound Myopic Astigmatism	547	49.00-76	47.12-166	3.77	11	6/6p	6/6P.	6/6P.	NIL	9 months 3 weeks
4	710904	19	F	LE	6/60.	LE -5.00/-1.00x70	5.5	6/6.	Normal	Compound Myopic Astigmatism	481	45.37-152	44.87-62	3.3	11.5	6/6P.	6/6.	6/6.	NIL	4 weeks
5	733184	28	M	RE	3/60.	RE -14.00/-1.00x40	14.5	6/9.	Myopic fundus	Compound Myopic Astigmatism	573	44.75-144	43.62-54	4.26	12	6/6.	6/6.	6/6.	NIL	3 months
6	740026	22	F	LE	5/60.	LE -9.00/-0.50x170	9.25	6/9.	Temporal crescent	Compound Myopic Astigmatism	503	43.62-80	42.87-170	3.3	11	6/6P.	6/6P.	6/6P.	NIL	5 weeks
7	678160	28	M	LE	6/60.	LE -4.50/-2.25x155	5.62	6/12p	Normal	Compound Myopic Astigmatism ,	428	54.5-68	51.75-158	3.8	11.25	6/24.	6/12P	6/9P.	NIL	2 month 1 week
8	760820	38	F	RE	3/60.	RE-15 Dsph	15	6/6.	Tilted disc with Temporal crescent	Simple Myopia	553	43.25-110	42.62-20	3.29	12	6/6.	6/6.	6/6.,	NIL	1 month
9	740378	28	M	RE	5/60.	RE -11.00/-1.00x10	11.5	6/12p	Normal	Compound Myopic Astigmatism	562	46.62-94	44.00-4	3.73	11	6/9P	6/12P	6/12P	NIL	4 months
10	637148	22	M	RE	3/60.	RE-5.25/-2.00x20	6.25	6/12p	Temporal crescent	Compound myopic astigmatism	419	41.37-114	39.12-24	2.81	10.5	6/9p	6/9p	6/9P.	NIL	1 month 2 weeks

11	722715	18	F	RE	2/60.	RE-18.00	18	6/12.	Normal	Compound Myopic Astigmatism	512	45.62-180	45-90	2.92	11	6/6.	6/6.	6/6.	NIL	1 month
				LE	2/60.	LE -19.00/-0.25x145	19.12	6/12.	Normal	Compound Myopic Astigmatism	512	45.62-180	45-90	3.42	11	6/9p	6/9P.	6/9P.	NIL	5 months
12	699966	39	M	RE	3/60.	RE-17.00/-1.00x10	17.5	6/9.	Posterior staphyloma	Compound Myopic Astigmatism	549	44.12-110	43.62-20	3.4	11.25	6/9P.	6/6P.	6/6P.	NIL	11 months
				LE	3/60.	LE -16.75/-0.75x160	17.12	6/9.	Posterior staphyloma	Compound Myopic Astigmatism	554	46.62-78	44.12-168	3.39	11.25	6/9P.	6/6P.	6/6P.	NIL	11 months
13	696919	22	F	RE	3/60.	RE-5.50/-0.50x180	5.75	6/6.	Normal	Compound myopic astigmatism	506	48.50-88	47.12-178	3.31	11.5	6/6.	6/6.	6/6.	NIL	5 weeks
				LE	3/60.	LE-5.50/-0.50x160	5.75	6/6.	Normal	Compound myopic astigmatism	509	48.50-96	47.50-6	3.45	11.5	6/6.	6/6.	6/6.	NIL	5 weeks
14	703424	28	F	RE	5/60.	RE -14.00/-2.00x18	15	6/6.	Normal	Compound myopic astigmatism	476	48.37-108	46.12-18	3.08	12	6/6.	6/6.	6/6.	NIL	5 weeks
				LE	5/60.	LE -14.00/-2.00x180	15	6/6.	Normal	Compound Myopic Astigmatism	477	48.12-112	46.5-22	3.56	12	6/9P.	6/9.	6/9.	NIL	4 weeks
15	704012	25	M	RE	3/60.	RE-10.00/-2.00x180	11	6/6.	Normal	Compound Myopic Astigmatism	477	48.87-98	46.89-8	3.08	11	6/18.	6/9p	6/9P.	NIL	1 month
				LE	3/60.	LE-13.00/-2.00x180	14	6/9.	Normal	Compound Myopic Astigmatism	476	49.25-98	46.87-4	3.1	11.5	6/18.	6/9p	6/9P.	NIL	1 month
16	718347	24	F	RE	2/60.	RE -12.00 Dsph	12	6/9.	Normal	Simple Myopia	517	45.00-90	44.87-180	3.72	11	6/6p	6/6P.	6/6P.	NIL	6 weeks
				LE	2/60.	LE-10.00/-1.00x180	10.5	6/9.	Normal	Compound Myopic Astigmatism	519	45.00-90	44.87-180	3.73	11	6/6p	6/6P.	6/6P.	NIL	6 weeks
17	746556	20	F	RE	6/60.	RE-11.00/-1.50x5	11.75	6/9.	Normal	Compound Myopic Astigmatism	544	46.87-112	44.75-22	3.21	11	6/6p	6/6p	6/6p	NIL	5 months
				LE	4/60.	LE -10.00/-2.00x175	11	6/9.	Normal	Compound Myopic Astigmatism	551	47.37-94	44.62-4	3.71	11	6/6P	6/9.	6/9.	NIL	5 months

18	748407	21	F	RE	2/60.	RE -19.50/-1.25x17	20.75	6/12p	Peripapillary Atrophy	Compound Myopic Astigmatism	523	45.00-100	43.75-10	2.98	12	6/9p	6/9P	6/9P.	NIL	3 months
				LE	2/60.	LE -19.75/-1.50x15	20.5	6/12.	Peripapillary Atrophy	Compound Myopic Astigmatism	523	44.87-100	43.12-10	2.98	12	6/12.	6/9p	6/9P.	NIL	3 months
19	723556	19	M	RE	2/60.	RE -10.50 Dsph	10.5	6/6p	Lattice degeneration	Simple Myopia	577	43.12-90	42.87-180	4.04	12	6/6.	6/6.	6/6.	NIL	9 months
				LE	2/60.	LE-9.75/-0.75x180	10.12	6/6p	Lattice degeneration	Compound Myopic Astigmatism	563	43.25-94	42.87-180	4.04	12	6/6.	6/6.	6/6.	NIL	9 months
20	722708	22	F	RE	5/60.	RE-7.25/-0.75x30	7.62	6/6p	Normal	Compound Myopic Astigmatism	462	44.87-108	43.75-18	3.66	12	6/6.	6/6.	6/6.	NIL	7 months 1 week
				LE	5/60.	LE-6.75/-1.00x170	7.25	6/6p	Normal	Compound Myopic Astigmatism	464	45.37-84	44.00-174	4.21	12	6/6P.	6/6.	6/6.	NIL	7 months 1 week
21	701209			RE	5/60.	RE -8.00 Dsph	8	6/9.	Normal	Simple Myopia	499	47.87-118	47.00-168	3.14	11.75	6/9P.	6/6P.	6/6P.	NIL	1 month
				LE	5/60.	LE -9.00 Dsph	9	6/9.	Normal	Simple Myopia	499	47.00-28	46.00-78	3.56	11.75	6/9P.	6/6P.	6/6P.	NIL	1 month
22	731642	19	M	RE	1/60.	RE-20Dsph/-2.00x1	21	6/24.	Peripapillary Atrophy	Compound Myopic Astigmatism	529	47.50-96	44.87-6	3.11	11	6/36.	HM	1/60.	GLAU	4 months
				LE	1/60.	LE-18.75Dsph/-2.00	19	6/12p	Peripapillary Atrophy	Compound Myopic Astigmatism	531	46.75-80	45.00-170	3.079	11	6/12.	6/24.	6/12p	NIL	4 months
23	761071	22	F	RE	2/60.	RE-13 Dsph	13	6/9p	Lattice degeneration	Simple Myopia	509	46.25-90	47.00-74	2.98	11.25	6/9.	6/9.	6/6P.	NIL	2 months
				LE	5/60.	LE -9.00/-1.00x150	10	6/9p	Lattice degeneration	Compound Myopic Astigmatism	507	46.00-180	45.62-164	2.97	11.25	6/9.	6/9.	6/6P.	NIL	2 months
24	760482	24	F	RE	5/60.	RE-12.25/0.50x25	12.5	6/12.	Lattice degeneration	Compound myopic astigmatism	520	45.37-106	45.37-90	3.52	11.5	6/9.	6/9.	6/9.	NIL	1 month
				LE	5/60.	LE-9.00/-1.25x180	12.87	6/9.	Lattice degeneration	Compound myopic astigmatism	516	44.50-16	44.62-180	3.52	11.5	6/6.	6/6.	6/6.,	NIL	1 month

25	750534	27	F	RE	6/60.	RE-7.50 Dsph	7.5	6/6.	Normal	Simple Myopia	495	46.75-80	48.37-98	3.3	11	6/6.	6/6.	6/6.	NIL	1 month
				LE	6/60.	LE -7.50/-1.00×180	8	6/6.	Normal	Compound Myopic Astigmatism	482	46.12-170	46.87-8	3.33	11	6/6.	6/6.	6/6.	NIL	1 month